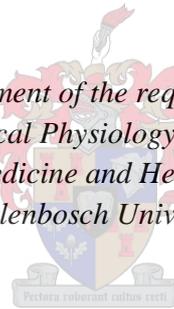


CHANGES IN HYO-LARYNGEAL ELEVATION POST- PHARYNGEAL ELECTRICAL STIMULATION

By

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March 2015

DECLARATION

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own, original work, that I am the authorship owner thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

Tobias Johannes Basson

Date: _17 February 2015_

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ABSTRACT

Swallowing disorders are prevalent in many elderly individuals and are common amongst individuals suffering from neurological diseases. These individuals are affected from slight swallowing difficulty to total swallowing inability. In severe cases this may cause aspiration pneumonia, dehydration, malnutrition and ultimately death. Swallowing disorders can be diagnosed and treated to increase quality of life. New treatment strategies to understand the pathophysiology and impaired swallowing response are needed.

Neuromuscular electrical stimulation is used as rehabilitation method in various disciplines. This method of rehabilitation of physiological dysfunction is used in treating swallowing disorders and has become a focus for current research. To understand the effect of electrical stimulation to the swallowing centre it is proposed to study its mechanism on normal swallowing musculature. The outcome of the effect that electrical stimulation has on healthy individuals may possibly be used to extrapolate to clinical settings and its benefit for modern dysphagia rehabilitation.

The purpose of this study was to report on the hyo-laryngeal movement pattern of young healthy, male and female, individuals and to measure the effect of a single neuromuscular electrical stimulation session on the hyo-laryngeal complex of 22 young healthy individuals. Lastly, the aim was to determine the detraining or lasting effect on the hyo-laryngeal swallowing complex of a single neuromuscular electrical stimulation session.

The study reported on baseline hyo-laryngeal complex movement patterns by measuring the anterior movement and elevation of the hyo-laryngeal complex through the use of videofluoroscopy swallow study. Analysis of these measurements were done to report on the effect of electrical stimulation on the hyo-laryngeal complex movement pattern pre- and post- electrical stimulation. Significant changes were revealed with elevation of the hyo-laryngeal complex, however no significant effects could be found with anterior movement of the hyo-laryngeal complex pre- and post- electrical stimulation. It was found that elevation of the hyo-laryngeal complex lowered after a single electrical stimulation session. The hyo-laryngeal complex movement pattern remained similar between genders. Lastly it was found that a single electrical stimulation session showed significant reversibility towards baseline levels. This might be related to muscle fatigue and one would need to take into account muscle recovery for future research.

Keywords: Swallowing disorders, neuromuscular electrical stimulation, hyo-laryngeal complex.

OPSOMMING

Sluk versteurings is algemeen onder bejaardes asook individue wat ly aan neurologiese siektes. Hierdie individue word geaffekteer deur matige sluk probleme tot totale sluk onvermoë. In ernstige gevalle kan dit aanleiding gee tot aspirasie longontsteking, dehidrasie, wanvoeding en selfs dood. Sluk versteurings kan gediagnoseer en behandel word om die kwaliteit van lewe te verbeter. Dit is daarom noodsaaklik om die patofisiologiese en verswakte sluk reaksie te verstaan om sodoende nuwe behandeling strategieë te ontwikkel.

Neuromuskulêre elektriese stimulasie word gebruik as rehabilitasie tegniek in verskeie dissiplines. Hierdie metode van behandeling van fisiologiese disfunksie word ook gebruik in die behandeling van sluk afwykings en geniet tans baie navorsings aandag. Om die effek van elektriese stimulasie op die sluk sentrum te verstaan word dit dus voorgestel dat die meganisme op die normale sluk spierstelsel bestudeer word. Hierdie bevindinge kan dus moontlik toegepas word op persone met sluk afwykings en sodoende meer effektiewe rehabilitasie tegnieke bevorder.

Die doel van hierdie studie was om die effek op die hyo-laringeale bewegings patroon van jong, gesonde, manlike en vroulike individue te bestudeer, asook om verslag te doen oor die uitwerking van 'n enkele neuromuskulêre elektriese stimulasie sessie op die hyo-laringeale kompleks van 22 jong, gesonde individue. Laastens was die doel van hierdie studie ook om die blywende effek van 'n enkele sessie neuromuskulêre elektriese stimulasie op die sluk sentrum te bepaal.

Die studie het basislyn hyo-laringeale kompleks bewegings patrone gerapporteer deur die voorwaartse asook opwaartse beweging van die hyo-laringeale kompleks te meet deur gebruik te maak van videofluoroskopie sluk studies. Ontleding van hierdie metings is gedoen om die uitwerking van elektriese stimulasie op die hyo-laringeale kompleks bewegings patroon voor en na elektriese stimulasie te bepaal. Beduidende veranderinge is in die opwaartse beweging van die hyo-laringeale kompleks gevind, alhoewel geen veranderinge gevind is in die voorwaartse beweging van die hyo-laringeale kompleks voor en na elektriese stimulasie nie. Daar is vasgestel dat die opwaartse beweging van die hyo-laringeale kompleks verlaag het na 'n enkele elektriese stimulasie sessie. Verder het die hyo-laringeale kompleks bewegings patroon geen beduidende verskille tussen geslagte getoon nie. Laastens is bevind dat 'n enkele elektriese stimulasie sessie beduidende omkeerbaarheid terug na basislyn vlakke van beweging toon. Dit kan verband hou met die uitputting van die hyo-laringeale spiere as gevolg van die elektriese stimulasie en toekomstige navorsing sal dus uitputting, asook die tempo van herstel in ag moet neem.

Sleutel Woorde: sluk versteurings, neuromuskulêre elektriese stimulasie, hyo-laringeale kompleks.

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ABBREVIATIONS

ALARA	As Low as Reasonable Achievable
ATPase	Adenosinetriphosphatase
DICOM	Digital Imaging and Communications in Medicine
FDA	Food and Drug Administration
ICF	Informed Consent Form
IRB	Institutional Review Board
HLC	Hyo-laryngeal Complex
LES	Lower Esophageal Sphincter
MBS	Modified Barium Swallow
NG	Nasogastric
NMES	Neuromuscular Electrical Stimulation
PACS	Picture archiving and Communication System
PEG	Percutaneous Endoscopic Gastrostomy
SD	Standard Deviation
SLT	Speech-Language Therapists
SEM	Standard Error of the Mean
SUMC	Stellenbosch University Medical Campus
UES	Upper Esophageal Sphincter
VFSS	Videofluoroscopic Swallow Study
TAH	Tygerberg Academic Hospital

CHAPTER 1: INTRODUCTION

1.1. Overview

The aim of the study is to determine the effect of neuromuscular electrical stimulation (NMES) on the hyo-laryngeal complex (HLC) movement in healthy young adults. Difficulty in swallowing (dysphagia) is a serious symptom that can lead to pneumonia, malnutrition, dehydration, reduced quality of life and death (Cichero & Clavé, 2012). Dysphagia can be diagnosed and treated, but requires a multidisciplinary approach to be effective (Cichero & Clavé, 2012). However, no standardized dysphagia protocols exist that establish sustained improvement in the treatment outcome, leaving dysphagia practitioners to determine their own protocol for treatment (Krisciunas, Sokoloff, Stepas & Langmore, 2012).

As proposed by Davies (2012) in her thesis; dysphagia rehabilitation methods originated in the 18th century, but none proved successful (Stokes, 1833). In 1980, the use of alternative feeding modalities such as percutaneous endogastric (PEG) or nasogastric (NG) tubes that bypass the impaired oropharynx (Robbins et al., 2008) was introduced. In the 1990s, the focus of management had shifted drastically to focus more on mechanisms that overcome the swallowing difficulty. As indicated by Davies (2012) such methods include advising patients to change their head position in order to protect the airway during swallowing, or changing the bolus viscosity, volume or texture to aid the flow of the bolus through the oropharynx. These compensatory techniques improved the patient's prognosis and resulted in symptoms, such as tracheal aspiration, to be immediately minimised (Kuhlemeier, Palmer, & Rosenberg, 2001).

Also pointed out by Davies (2012) there are however certain drawbacks when implementing these adaptive approaches: these strategies have to be applied for every swallow, no lasting physiological change is achieved. As reported by Robbins et al. (2008) and Davies (2012), the patients often report that the pleasure in eating is diminished. In response to these ongoing issues and non-sustainable outcomes, patient care has continued to evolve from a purely compensatory/adaptive approach to techniques that attempt in achieving a more permanent shift in underlying swallowing physiology. Rehabilitation methods such as swallowing exercises and electrical stimulation have been developed over the past three decades and are now available as a treatment option (Jayasekeran et al., 2010, Davies, 2012). It is known that the muscles involved in mastication and swallowing do adapt in response to increases in stimulation load (Thompson, Throckmorton, & Buschang, 2001; Vincent, Shanely, Stewart, Demirel, Hamilton, Ray, & Powers, 2002). Dysphagia rehabilitation may be either direct (when food and liquid is used) or indirect (when no food or liquid is used). The ultimate aims of these newer approaches are to promote positive health outcomes, such as shortened lengths of stay for hospitalized patients, and to reduce the risks for pneumonia (Neumann, Bartolome, Gudrun, Buchholz & David, 1995; Steele et al., 2011).

Neuromuscular electrical stimulation (NMES) is a modern form of treatment for swallowing disorders aimed at assisting in recovery of motor control and strengthening of weak muscles (Ludlow, 2008). Dr. Shaheen Hamdy, a research gastroenterologist, highlighted that while both brain hemispheres are involved in swallowing control; most people have this function lateralised to a dominant hemisphere. This finding explained why some individuals develop swallowing problems post stroke, whereas others do not. (Hamdy, 1996). Some individuals thus recovered from dysphagia due to functional reorganization (Hamdy, Aziz, Rothwell, Hobson, & Thompson, 1998). Pharyngeal stimulation is shown to induce functional reorganization which leads to improved swallowing performance; this shows a direct relationship between stimulation, cortical excitability and improvement in swallowing function (Fraser et al., 2002). Pharyngeal stimulation treatment in general was clinically proven; not only to improve swallowing function, but also to reduce the risk of aspiration and hospitalization times (Jayasekeran et al. 2010; Steele et al., 2011).

There is insufficient understanding and research regarding the effects of rehabilitation exercises on the swallowing muscles (Suiter, Leder & Ruark, 2006; Huckabee & Doeltgen, 2007; Ney, Weiss, Kind & Robbins, 2009). Researchers are urged to develop new strategies in order to better understand the pathophysiology, which will in turn lead to improved treatments for impaired swallowing responses (Carnaby-Mann & Crary, 2007; Burkhead, Sapienza & Rosenbek, 2007; Cichero & Clavé, 2012). Intramuscular NMES has been investigated, but requires additional research on the effects on swallowing performance as rehabilitation (Heather, Cathy, Arvedson, Schooling, & Frymark, 2009). In summary current literature shows extensive research done on surface NMES to the neck, but evidence of its efficacy is still lacking in the literature.

Another important factor to take into account when studying swallowing function is age. Literature shows that swallowing function changes with age (Rademaker, Pauloski, Colangelo & Logemann, 1998). It is shown that sphincter opening, relaxation and pharyngeal transit times are delayed in the elderly (Shaw, Cook, Gabb, Holloway, Simula, Panagopoulos & Dent, 1995). Recent literature (Youngsun & Gary, 2014) confirms that as age increases we observe a decrease in the anterior displacement of the hyoid bone, whereas its elevation is not affected by age. It also suggests that muscle weakness is responsible for such change observed in the hyo-laryngeal muscle complex and that it is not gender specific.

It is therefore important to make use of healthy individuals with normal swallowing function to observe what effect NMES has on the hyo-laryngeal muscle complex, so that we can evaluate and apply the findings to individuals with swallowing impairment.

The hypothesis of the study is to determine if a single NMES-session has an effect on the movement pattern of the HLC in young healthy adults.

1.2. Aim and Objectives of the Study

The aim of the study is to determine the extent to which NMES influences the movement of the HLC in healthy young individuals.

The research objectives are to determine:

- 1.2.1. Baseline measurements regarding HLC movement in young healthy individuals prior to NMES.
- 1.2.2. The effect of NMES on the movement patterns of the HLC after a 14 minute NMES session.
- 1.2.3. The detraining effects of NMES on the movement patterns of the HLC.

1.3. Thesis Outline

Dysphagia is a severe health condition amongst many patients, known to lead to serious respiratory and nutritional complications that can lead to death (Cichero & Clavé, 2012). Chapter 2 contains an in depth overview of the normal and pathological swallowing, important anatomical and physiological structures, and treatment methods for dysphagia. Chapter 3 will consist of the methodology while the results will be discussed in chapters 4 and 5. This will be followed by conclusion and future recommendations and/or applications in chapter 6.

1.4. Summary

The literature shows that dysphagia is a major concern without clearly defined rehabilitation methods being available (Krisciunas et al., 2012). It is proposed that a multidisciplinary approach combined with modern treatment methods such as NMES might be the answer towards more sustainable rehabilitation outcomes. However, the effects of NMES on the swallowing muscles remain unclear. To gain a better understanding regarding the pathophysiology of the swallow, it is proposed to include healthy individuals in this study as opposed to swallowing-impaired individuals: such individuals may react differently to NMES when compared to healthy individuals. Therefore, data generated from healthy individuals will neutralise this predicted variability of the human swallowing function post NMES of swallowing impaired individuals. Our data generated may enable researchers to gain a better understanding of the pathophysiology of the swallow in order to develop new rehabilitation methods for implementation to the swallow impaired patient.

CHAPTER 2: LITERATURE REVIEW

2.1. Physiology and Anatomy of the Swallowing Mechanism

A brief background on the fundamentals of muscle physiology is important for the purpose of this study. In this section the different types of muscle fibres regarding swallowing muscles and the relevance thereof will be discussed. Swallowing muscle structure is discussed and important concepts such as muscle contraction and innervations thereof will be presented.

2.1.1. Muscle Fibre Types

Two types of muscle fibres are grouped in the human body; type I and type II, also known as slow and fast twitch fibres. These muscle fibres also constitute the swallowing complex, as shown in Table 1. They have distinctive metabolic and functional properties when recruited. Type I (slow-oxidative) fibres contain large amounts of mitochondria, dense in capillaries and high concentration of myoglobin, resulting in high resistance to fatigue (Powers & Howley, 2007). Type II (fast-glycolytic) fibres contains small amount of mitochondria and highest myosin ATPase activity. Type II fibres can however be classified into IIa and IIx fibres. Type IIa fibres are an intermediate fibre and can adapt to the same oxidative characteristics as type I fibres. All three fibre types are present in all muscles in the human body, but differ in the distribution thereof from muscle to muscle. Fibre type distribution is related to the function of the specific muscle. Static muscle function requires a higher amount of type I fibres and dynamic function in the muscles require a higher amount of type II muscle fibres.

Table 1

Muscle Fibre Type Distribution of the Swallowing Complex

Fibre Type	Type I	Type II x/a
Muscle	Levator palatine, Inferior fibres of lower pharyngeal constrictors, Cricopharyngeus	Intrinsic tongue muscles, Supra- and infrahyoid muscles, Digastric muscles, Middle pharyngeal constrictors, Outer layer of inferior pharyngeal constrictors

Note: Adapted from Wijting & Freed, 2003. The histochemical distribution of the swallowing muscles.

It is shown that the muscle composition of the human jaw comprises of both Type I and Type II muscle fibres (Korfage, Koolstra, Langenbach, & Van Eijden, 2005). The composition of muscle fibre percentage is determined by the individual's genetic make-up, hormone levels in the blood and exercise habits (Powers & Howley, 2007). However, biopsy studies indicate that the majority of swallowing muscles contain type II muscle fibres (Wijting & Freed, 2003). Muscle fibre composition

of the muscle is very important to determine its role regarding performance in endurance or strength (Powers & Howley, 2007). In normal muscle contraction, type I muscle fibre recruitment occurs prior to recruitment of type II muscle fibres. Type II muscle fibres are recruited when the load increases or during dynamic movements of swallowing. The literature has also shown that swallowing muscles largely comprise of skeletal muscle, which is abundant in oxidative type II fibres (Tellis, Thekdi, Rosen & Sciote, 2004). Table 2 provides an overview of the types I and II muscle fibre histochemical differences.

Table 2

Physiological, Structural and Biochemical Characteristics of the Major Histochemical Fibre Types

Characteristics	Fibre types		
	Type I	Type IIa	Type IIb
<i>Physiological</i>			
Function	Sustained forces, as in posture	Powerful, fast movements	
Motor neuron firing threshold	Low	Intermediate	High
Motor unit size	Small	Large	Large
Firing pattern	Tonic, low- frequency	Phasic high-frequency	
Maximum shortening velocity	Slow	Fast	Fast
Rate of relaxation	Slow	Fast	Fast
Resistance to fatigue	Fatigue resistant	Moderate fatigue resistant	Fatigue susceptible
Power output	Low	Intermediate	High
<i>Structural</i>			
Capillary density	High	Moderate	Low
Mitochondrial volume	High	Intermediate	Low
Z-band	Broad	Narrow	Narrow
T and SR systems	Sparse	Restricted	Extensive
<i>Biochemical</i>			
Myosin ATPase activity	Low	Intermediate	High
Oxidative metabolism	High	Intermediate	Low
Anaerobic glycolysis	Low	Intermediate	High
Calcium transport ATPase	Low	Intermediate	High

Note: Taken from Gray's Anatomy the Anatomical Basis of Clinical Practice Fortieth Edition, Copyright 2008 by Elsevier Limited.

2.1.2. Muscle Structure

Skeletal muscle is commonly referred to as voluntary muscles, which are involved in involuntary actions of the swallow (Standring, 2008). Skeletal muscles refer to the muscles that attach to the skeleton structure of the human body creating lever systems in-between bony structures to provide functional movement. Skeletal muscle is also referred to as striated muscles, describing their microscopic cross-striated appearance of myosin and actin filament arrangement as shown in Figure 1.

Skeletal muscles consist of muscle fibres, which contain contracting proteins, organised in cylindrical myofibrils and have a powerful contraction capability. Myofibrils are made up of sarcomeres which are formed by the contractile proteins, sliding past each other during muscle contraction and relaxation. The sarcomeres consist of thick filament made up of myosin and the thin filament made up of actin, see Figure 1. These proteins bind and release with the presence of troponin to perform a muscle contraction and relaxation (Rhoades, 2013).

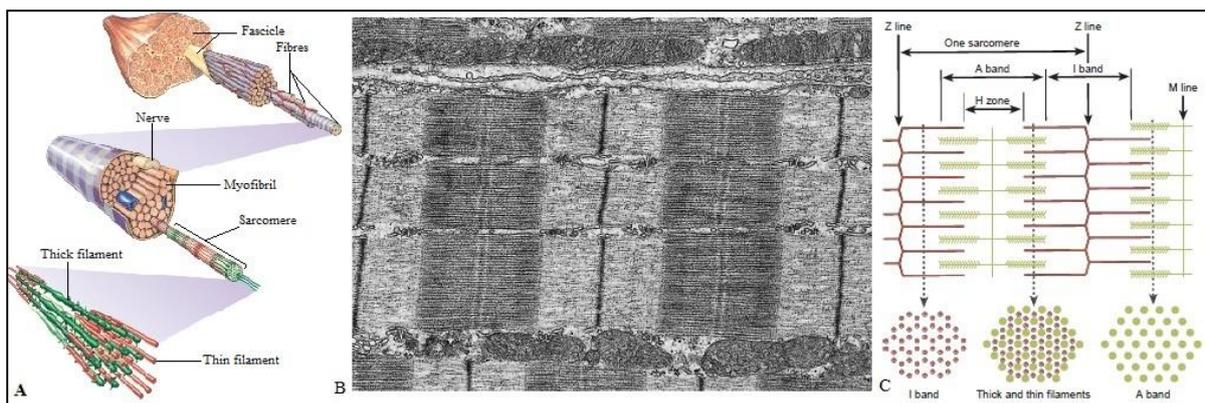


Figure 1. Structure and Levels of Organization of Skeletal Muscle. Adapted from Gray's Anatomy the Anatomical Basis of Clinical Practice Fortieth Edition, Copyright 2008 by Elsevier Limited.

Muscle contraction presents itself either as dynamic or static force generation. Dynamic force generation is when a muscle action results in movement of body parts classified as concentric or eccentric. Concentric muscle action involves the shortening of the muscle and eccentric, the lengthening of the muscle. Static force generation occurs during isometric muscle action, when force is generated but the muscle remains unchanged in its length (Powers & Howley, 2007). In research published by Carnaby-Mann and Crary (2011), the authors found that the swallowing muscles are plastic, responsive and can be re-trained for the purpose of preventing and rehabilitating swallowing disorders.

2.1.3. Muscle Innervation

For a muscle contraction to take place an action potential needs to be generated. Somatic motor nerves are responsible for the innervations of skeletal muscle in the human body; it forms part of the peripheral nervous system and carries motor and sensory information to and from the central nervous system. Such stimuli causes a motor neuron to be excited, this initiates an action potential along the axon, and reaches each muscle fibre it innervates (Rhoades, 2013). Figure 2 illustrates the chain of events when the action potential arrives at the motor end plate and cause acetylcholine, a neurotransmitter molecule, to be released into a synaptic cleft between the nerve ending and sarcolemma (Rhoades, 2013). Acetylcholine binds to receptors on the muscle fibre and cause permeability of sodium and potassium channels in the cell membrane. Sodium enters the muscle cell while potassium leaves the muscle cell, according to their electrochemical gradient. This causes action potentials to be generated at the postsynaptic junction and spread over the sarcolemma. The action potential is conducted down via T-tubules and cause calcium ions to be release from the sarcoplasmic reticulum into the cytosol of the cell. The release of calcium ions triggers the cross bridge cycle of the muscle, calcium ions bind partially to troponin allowing actin and myosin to bind and cause muscle contraction. Relaxation occurs when calcium ion concentration decreases (Rhoades, 2013).

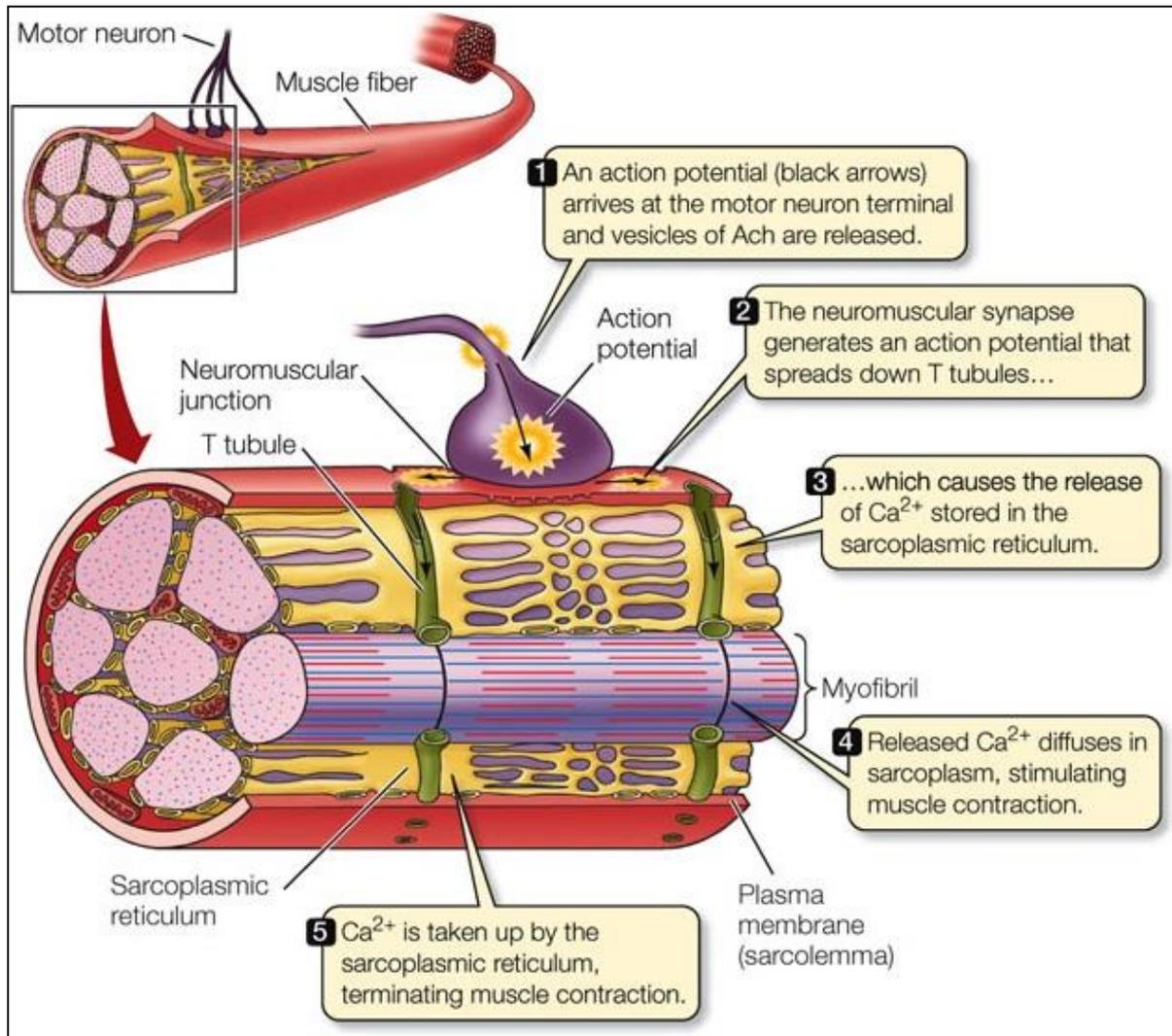


Figure 2. Neuromuscular Junction. This figure illustrates the action potential reaches the muscle to initiate a muscle contraction. Taken from Life Science of Biology Eighth Edition. Copyright 2007 by Sinaur Associates Incorporated.

2.2. Swallowing Mechanism

Healthy swallowing is characterised by several phases, as shown in Figure 3. It is a complex mechanism coordinated by numerous muscles, nerves and anatomical structures. To conceptualise the complex mechanism of swallowing Logemann (1998) identified four phases in the coordinated chain of events. In this section each phase of swallowing will be briefly explained as identified by Logemann (1998).

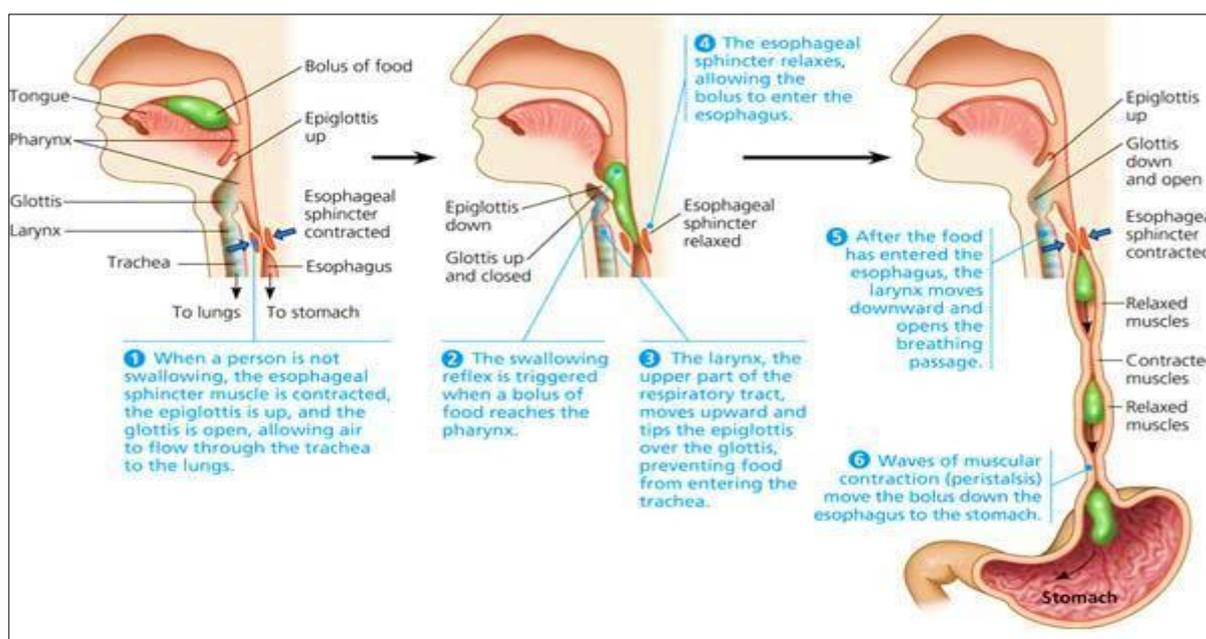


Figure 3. The Phases of Deglutition. This figure illustration the swallowing phases in detail. Retrieved from http://www.cikgurozaini.blogspot.com/2011_07_01_archive.html. Rozaini Othman, 2011.

2.2.1. Oral preparatory phase

The oral preparatory phase is when liquid or food is manipulated and tasted in the mouth and then broken down into a consistency ready for swallowing. Swallowing is driven by a pressure gradient initiated between different bio-functional compartments which starts at the; pressure chamber formed between the two dental arches (inter-occlusal compartment) of the mouth, area below the palatal vault forming negative pressure (subpalatal compartment) and esophagus (Engelke, Jung, & Knösel, 2011). The pressure differences, as the bolus moves through the different phases, are controlled by bio-functional valves (Kahrilas, Lin, Logemann, Ergun & Facchini, 1993). During the oral preparatory phase the pressure is controlled by the lips (obicularis oris muscles, anterior limit) and the linguo-palatal valve (posterior limit) which refers to contact between the anterior margin of the tongue and the hard palate, as shown in Figure 4.

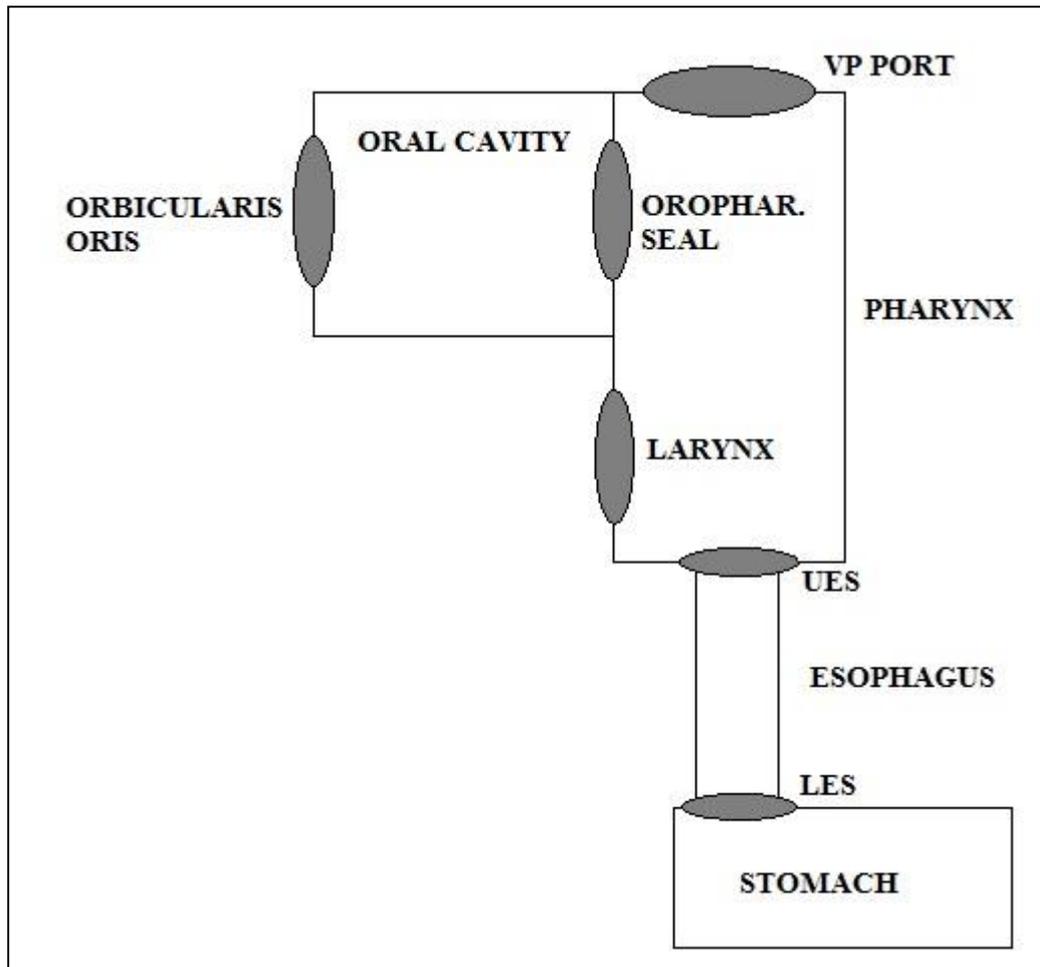


Figure 4. The Swallowing System. The figure illustrates the swallowing system as chambers and valves. Taken from VitalStim® Therapy Training Manual. Retrieved from <http://www.vitalstimtherapy.com>. Copyright 2006 by Yorick Wijting, PT and Mercy Freed, M.A.

The oral preparatory phase is voluntarily and consists of several actions, as shown in Table 3. Tongue mobility is the most important activity during this phase as it facilitates mastication, bolus formation and digestion. The tongue is innervated by the glossopharyngeal nerve and is responsible for the sensory relay, regarding the viscosity and volume of the bolus, to the brainstem and cortex. The oral preparatory phase is concluded when the tongue gathers around the bolus, elevates and makes contact with the lateral and maxillary alveolar ridges and pushes against the hard palate (Logemann, 1989).

Table 3*Neuromotor Behaviours Involved In the Oral Preparatory Phase*

Action	Muscles	Purpose
Lip closure	Orbicularis Oris	Closure of oral cavity to maintain pressure and prevent bolus from leaking out
Tension in cheeks and labial structures of the oral cavity	Orbicularis Oris, Buccinators, Superior pharyngeal constrictor	Create positive pressure in oral cavity, facilitate in bolus control and prevent bolus from entering sulci
Circular, lateral movement of the jaw	Masseter, Temporalis, Lateral and medial pterygoid	Bolus modification and control / mastication
Rolling lateral motion of the tongue	Intrinsic & extrinsic tongue muscles, Palatoglossus, Stylopharyngeus	Mixing bolus with saliva, gathering bolus
Pulling forward of the soft palate	Styloglossus, Superior pharyngeal constrictor, Hyo- & Palatoglossus	Creates positive pressure in the pharyngeal chamber

Note: Adapted from Logemann (1985). A summary of the neuromotor behaviours involved in the oral preparatory phase as identified.

2.2.2.Oral phase

The oral phase is when the bolus is propelled to the back of the mouth by means of an anterior to posterior rolling motion of the tongue and lasts for approximately one second (Shaker, Cooks, Dodds & Hogan, 1988). During the oral phase the tongue is gathered around the bolus and pushes it posterior against the hard palate in the oral cavity until it reaches the faucial arches, as shown in “1” in Figure 3. The buccinators and orbicularis oris muscles contract at this point to control the bolus from escaping the oral cavity (Logemann, 1975). Once the bolus has been sufficiently displaced along the hard palate to reach the faucial arches, it makes contact with the anterior faucial arch, posterior faucial arch and the posterior pharyngeal wall, as shown in Table 4. The swallowing reflex is an upper airway protection mechanism and consists out of afferent, central and peripheral components (Nishino, 2012). Stimulation in the soft palate area triggers the reflex, the pharyngeal phase is then triggered via cortical input (Logemann, 1989) and impulses are relayed to the swallowing centres in the brain via the glossopharyngeal nerve. During the oral phase pressure is generated by the linguo-palatal valve and velo-lingual valve as shown in Figure 4 (Santander, Engelke, Olthoff & Volter, 2013).

Table 4*Neuromotor Behaviours Involved in the Oral Phase*

Action	Muscles	Purpose
Tongue base elevates anterior-posterior	Styloglossus, Superior pharyngeal constriction, Hyo- & Palatoglossus	Creates positive pressure in the pharyngeal chamber
Velum lowers and makes contact with base of the tongue to create oropharyngeal seal	Levator veli palate, Superior pharyngeal constrictor	Prevents bolus from entering the pharynx

Note: Adapted from Logeman (1985). A summary of the purposes, actions and muscles involved in the oral phase of swallowing.

2.2.3. Pharyngeal phase

The pharyngeal phase is triggered when the bolus passes the faucial arches. It is controlled reflexively and characterized by the passing of the bolus through the pharynx, which lasts for approximately one second (Sonies, Parent, Morrish & Baum, 1988). The pharyngeal phase is characterized by four neuromuscular events that occur as the swallowing reflex is triggered, i.e. when the bolus passes the faucial arches. According to Logemann (1985) these four neuromuscular activities are; velopharyngeal closure, peristaltic contraction in the pharyngeal constrictors, laryngeal closure and cricopharyngeal relaxation, as shown in Table 5. These four neuromuscular activities are under cortical control and are entirely involuntary. The bolus transit time through the pharynx lasts for approximately one second (Logemann, 1994) and each neuromuscular action occurs only for a fraction of the total transit time. Two very important anatomical structures known as the pharyngeal recesses play a critical part in the transit of the bolus through the pharynx. During the pharyngeal phase pressure is generated by the linguo-palatal valve and velo-lingual valve as shown in Figure 4 (Santander et al., 2013).

The pharyngeal recesses consist of the valleculae and the pyriform sinuses. The valleculae is a pocket formed by the attachment of the hyo-epiglottic ligament between the epiglottis and the hyoid bone. The pyriform sinuses are shaped by the attachment of the inferior constrictor muscles to the laryngeal cartilage of the larynx. The muscles attach anteriorly and laterally, forming pockets between the cartilage and muscle fibres laterally and posteriorly. During swallowing the bolus splits into two at the valleculae and passes down each side of the pharynx and through each of the pyriform sinuses. At the inferior aspect of the pyriform sinuses the cricopharyngeus muscle, also known as the upper esophageal sphincter (UES), is located. The cricopharyngeus / UES relax, thereby allowing the bolus to enter into the esophagus.

Table 5*Neuromotor Behaviours Involved in the Pharyngeal Phase*

Action	Muscles	Purpose
Soft palate (velum) elevates and creates velopharyngeal closure	Levator veli palatine, Superior pharyngeal constrictor	Approximates the wall of the nasopharynx, prevent bolus from entering the nasal cavity, maintain pressure to propel the bolus through the pharynx
Anterior-superior movement of the hyoid bone, anterior movement of the larynx, epiglottic deflection or inversion.	Suprahyoid & thyrohyoid muscles, Aryepiglotticus and Thyroepiglotticus muscles.	Enlarges the pharynx, exerts force, closes laryngeal vestibule and cricopharyngeus muscle relaxes, induces inversion of the epiglottis for further airway protection, and diverts bolus towards pyriform sinuses.
True and false vocal folds adduction	Vocal cord adductors	Closes entrance to the trachea
Hyo-laryngeal excursion (anterior-superior movement of the hyoid bone)	Suprahyoid & infrahyoid muscles	Closing laryngeal vestibule and cricopharyngeus muscle relaxes
Upper esophageal sphincter relaxes (UES)	Cricopharyngeus, Supra- & Infrahyoid, & Pharyngeal constrictors	Bolus enters esophagus

Note: Adapted from Logeman (1985). A summary of the purposes, actions and muscles of relevance for the pharyngeal phase of swallowing.

2.2.4. Oesophageal phase

The oesophageal phase is characterized by the passing of the bolus through the esophagus into the stomach and lasts on average for 8 to 20 seconds (Tutuian, Vela, Balaji, Wise, Murray, Peters, Shay & Castell, 2003). The esophageal phase of the swallow is defined as the point from which the bolus enters the esophageal sphincter at the proximal esophagus, which is located at the cricoid cartilage and UES. This phase of the swallow, as summarised in Table 6, is entirely under involuntary control and transit time of the bolus decreases to 2-4 centimetres per second (Schindler & Kelly, 2002). The cricopharyngeus muscle contracts to establish sustained UES closure, preventing regurgitation of the bolus back into the pharynx. The bolus is transported by peristaltic muscle action of the constrictor

muscles of the esophagus which consist of two layers of striated muscles as well as a middle and distal region entirely comprising out of smooth muscles. The outer muscles at the proximal region of the esophagus are arranged in a longitudinal fashion, whereas the inner muscles are arranged to contract in a circular or constricting fashion. This muscle arrangement is responsible for the peristalsis initiated in the esophagus to transport the bolus towards the stomach. As the bolus reaches the distal esophagus the LES relaxes and the bolus enters the stomach. It is shown that the LES is responsible for 90% of basal junction pressure and plays a valuable part in the swallowing process as shown in Figure 4 (Boeckxstaens, 2005).

Table 6

Neuromotor Behaviours Involved in the Esophageal Phase

Action	Muscles	Purpose
UES constricts	Cricopharyngeus, Supra- & Infrahyoids, & Pharyngeal shortners	Prevents bolus from moving back into the pharynx
Peristaltic motion of the esophagus	Esophageal constrictor muscles	Creates positive pressure in esophageal chamber to move bolus towards the stomach
Lower esophageal sphincter relaxes (LES)	Lower esophageal sphincter	Controls access to stomach

Note: Adapted from Logeman (1985). A summary of the purposes, actions and muscles involved in the esophageal phase of swallowing,

2.3. Neuromuscular Control of the Swallow

For the purpose of this study it is not only important to have a good understanding on neural control at the site of the swallowing muscles, but to understand the neural control on a central and peripheral level. The swallow consists of voluntary and involuntary components coordinated by specific regions in the cerebral cortex and brainstem. This means that swallowing is not a true reflex due to the fact that it is under partial control of the brainstem (Jean, 2001). However, over the last two decades valuable knowledge has been gained, revealing the relationship between these reflexive and volitional sensorimotor events which is of great relevance to improvement of diagnosis and treatment. It is believed that an underlying neural substrate network is responsible for a patterned response. This patterned response, accessed wilfully in the early stages of the swallow, has more treatment potential than aimed at a reflex (Robbins et al., 2008).

2.3.1. Neural Control

A central pattern generator is located in the medulla oblongata, whereas the dorsal medulla contains generator neurons responsible for triggering, shaping and timing of the swallow and the ventrolateral medulla contains switching neurons responsible for relay of swallow drive to the specific motor neurons (Jean, 2001). The cortical and subcortical regions of the brain are primarily responsible for the voluntary initiation of the swallow in the oral preparatory and oral phases (Jean, 2001). The brainstem is responsible for the involuntary phases, i.e. the pharyngeal and esophageal phases of the swallow. Both afferent (sensory) and efferent (motor) feedback makes swallowing possible. During the oral phase afferent impulses from receptors in the mouth and tongue gets relayed to the cerebral cortex via the trigeminal nerve (V), the glossopharyngeal nerve (IX) and the vagus (X) nerve. These three cranial nerves converge in the brainstem at the nucleus tractus solitaries. As shown in Table 7, the nucleus tractus solitaries is then responsible for interpretation of this afferent information and relays coordinated impulses via the specific cranial nerves to the muscles in order to generate the swallow. Another set of interneurons, known as the ventromedial group, are located in the nucleus ambiguus. The nucleus tractus solitaries, nucleus ambiguus and several other brainstem nuclei form a central pattern generator responsible for the oropharyngeal swallow (Jean, 2001).

Table 7

Neuromuscular Control of the Swallow

Phase	Cranial Nerve	Motor	Action	Sensory
Oral Preparatory Phase	Trigeminal (CN: V)	Temporalis Masseter Medial pterygoid Lateral pterygoid Tensor veli palatine Mylohyoid Anterior belly of digastric	Elevates, open, closes, retracts, depresses, mandible Stretches the soft palate, Elevates hyoid bone	Mandibular branch Maxillary branch (Mucus membranes of the mouth, cheeks and anterior two-thirds of the tongue)

Oral phase	Facial (CN: VII)	Orbicularis Oris, Zygomaticus Buccinators Posterior belly, Digastric, Stylohyoid	Lip closure Buccal tone Hyo-laryngeal excursion	Taste from anterior two-thirds of the tongue
Pharyngeal Phase	Glossopharyngeal (CN: IX)	Upper Pharyngeal Constrictor Stylopharyngeus	Pharyngeal constriction and shortening	Taste and sensation from the first-third of the tongue, the velum, the fauces and superior portion of the pharynx
	Vagus (CN: X)	Levator Veli Palatini, Palatoglossus, Pharyngeal constrictors, Intrinsic laryngeal muscles, Cricopharyngeus	Velopharyngeal closure, Tongue base retraction, Pharyngeal squeeze, Airway closure, UES opening and closure	Sensory information from the velum, posterior and inferior portions of the pharynx and larynx
	Hypoglossal (CN: XII)	Extrinsic and intrinsic tongue muscles, Thyrohyoid approximation through thyrohyoid and hyoid protraction through geniohyoid	Tongue mobility, Hyo-laryngeal elevation	

Esophageal Phase	Vagus (CN: X)	Esophageal muscles (Striated in proximal one-third and smooth in distal two-thirds of esophagus)	Esophageal motility	Sensory information from the sensation in the larynx and Esophagus
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Note: Adapted from Wijting & Freed, 2003. A summary of the neuromuscular control of the swallow.

2.3.2. Neural Plasticity

It is important to note that the brain has the ability to change the function of a particular neural substrate responsible for a specific behaviour (Cohen et al., 1998). This phenomenon is defined as neural plasticity (Cohen et al., 1998; Buonomano & Merzenich, 1998). A link exists between neural plasticity and behaviour remodelling after cortical injury, it remains unclear how it relates to swallowing behaviour rehabilitation (Robbins et al., 2008). The discovery that there is a relationship between the dominant pharyngeal region in the brain and the presence or absence of dysphagia in cortical stroke patients led to the conclusion that the swallowing system might be excellent for studying cortical plasticity (Hamdy & Rothwell, 1998; Teismann, Ringelstein & Dziewas, 2009; Humbert, 2010). Different forms of stimulation have been used to initiate neural plasticity; however electrical stimulation applied to the swallowing muscles has showed to support a plastic response (Hamdy et al., 1998; Humbert, 2005; Ludlow et al., 2007). Research urge that findings need to be taken with caution, and to note that neural changes may not always be accompanied by behavioural changes (Power et al., 2004). It is also pointed out that electrical stimulation outcome may be influenced by placement, intensity and duration of the stimulation (Robbins et al., 1998)

2.4. Biomechanics and Kinesiology of the Swallow

The temporomandibular joint is responsible for mastication and is primarily controlled by the masseter, medial- and lateral pterygoid and temporalis muscles (agonists). The temporomandibular joint is opened by both bellies of the digastric muscles (synergists). The literature identifies the kinetics of the hyoid bone and larynx as the most important when analysing swallowing (Perlman, Van Daele, Douglas & Otterbacher, 1995; Zu, Yihe & Zhenyu, 2011). Hyoid bone kinematics starts with superior kinesis of elevation which is then followed by anterior kinesis (Ishida, Palmer & Hiimae, 2002; Zheng, Jahn & Vasavada, 2012). Superior kinesis initiates slightly earlier than forward kinesis, however the superior and anterior peak is reached in synchrony with the expansion of the hypo pharynx and enables the bolus to pass through the pharynx. Laryngeal elevation is greater than that of the hyoid bone, while the hyoid bone moves a greater distance anteriorly than the larynx (Palmer, Drennan & Baba, 2000). At the onset of pharyngeal elevation, following suprahyoid muscle activation, the infrahyoid muscle contracts. The contraction of the supra- and infrahyoid muscles occurs in synergy and facilitate the hyoid bone and larynx to achieve upward kinesis (Burnett, Mann, Cornell & Ludlow, 2003).

As with all stages of swallowing, patterns of hyoid movement are dependent on the physical properties of the incoming bolus, i.e., the bolus volume and viscosity (Chi-Fishman & Sonies, 2002). Age and gender may also influence hyoid kinematics; men have greater cervical spine length and display less anterior hyoid movement (Molfenter & Steele, 2014). The participant's height should be taken into account with correction variations in measurements of structural displacement (Howden, 2004; Nagy et al., 2014).

2.5. Hyo-laryngeal Complex

The HLC includes the hyoid bone, thyrohyoid membrane, and laryngeal cartilages which serve as an attachment site for the cricopharyngeus that forms part of the upper esophageal sphincter (UES). As seen in Figure 5, other muscles attaching to the HLC, include the posterior digastric, the stylohyoid, and the long pharyngeal muscles, all of which have been identified as potential synergists to the movement of hyo-laryngeal excursion, however their roles have not been explicitly investigated as of yet (Pearson, Langmore, Yu & Zumwalt, 2013). Figure 5 clearly illustrates the hyoid bone is suspended from a sling of muscles attaching posteriorly at the styloid and mastoid processes of the cranium and anteriorly from the mandible (Wijting & Freed, 2003). The hyoid bone is attached to the larynx via multiple ligaments and the thyrohyoid muscle (Wijting & Freed, 2003). This combination of movements displaces the larynx away from the trajectory of an oncoming bolus, shortens the pharynx, and pulls open the otherwise closed UES to receive the ingested bolus. Hyo-laryngeal elevation occurs concomitantly with the opening of the UES sphincter and hyoid displacement is a critical component of swallowing by contributing to airway protection and facilitating UES opening.

Adequate anterior and superior hyoid excursion results in the epiglottis tilting to cover the vocal folds, preventing the bolus from entering the larynx. The hyoid bone moves anterosuperior by a half or one cervical vertebra, and moves between the anterior mandible and posterior mandibular ramus. The thyroid cartilage moves towards the hyoid and results in a total excursion of approximately 1–2 times the height of the cervical vertebra (Wijting & Freed, 2003). In healthy individuals the onset of hyoid bone displacement initiates the pharyngeal phase of swallowing. This displacement is caused by contraction of the suprahyoidal muscles. Suprahyoidal muscle contraction initiates superior laryngeal movement, producing anterior traction on the cricoid. This traction results in the opening of the UES as (Dodds, Shaker, Dantas, Hogan & Arndorfer, 1990).

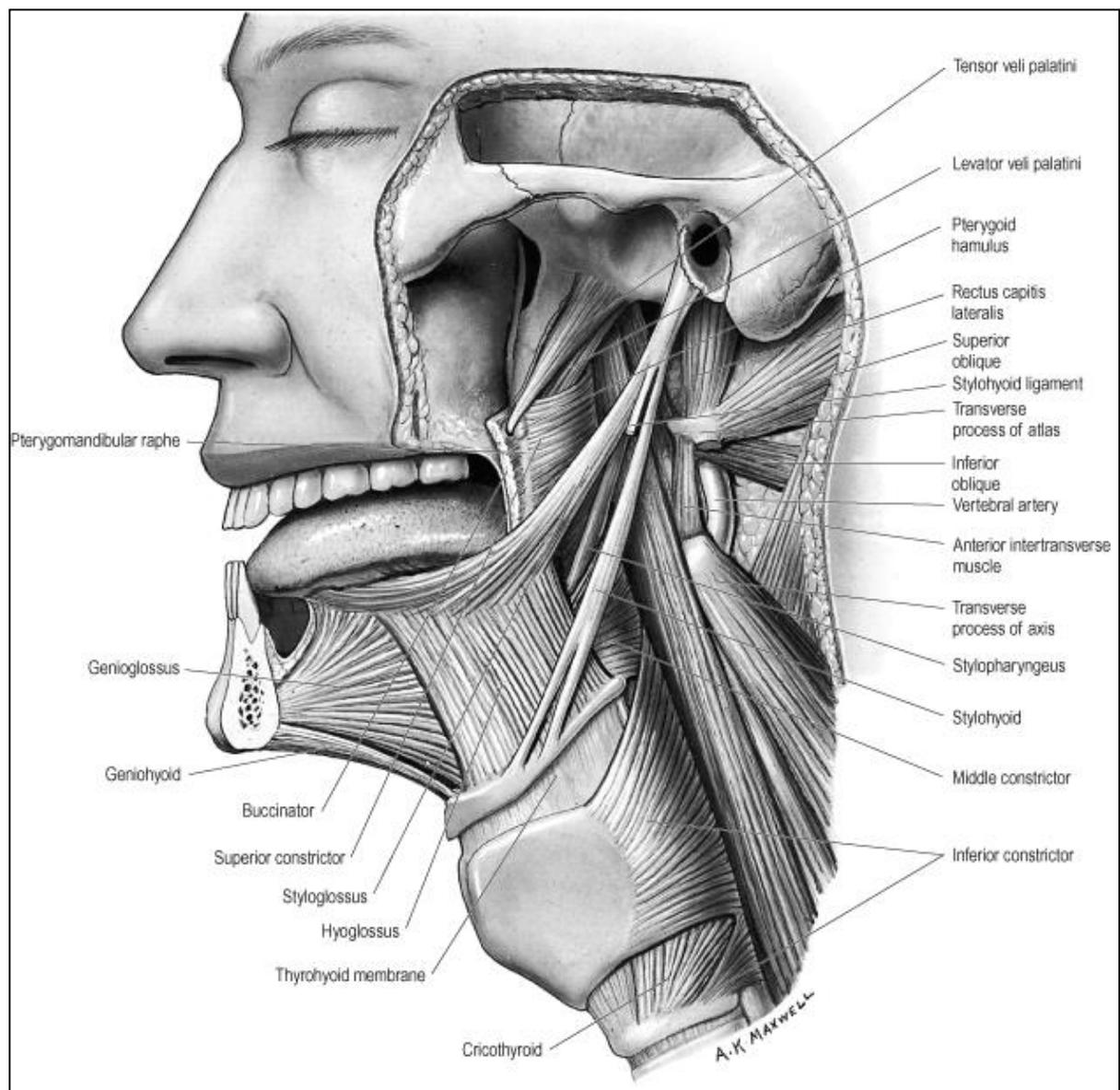


Figure 5. The hyo-laryngeal complex. The figure illustrates the bony and muscular structures of the hyo-laryngeal complex. Taken from Gray's Anatomy The Anatomical Basis of Clinical Practice Thirty-ninth Edition, Copyright 2005 by Elsevier Limited.

2.6. Dysphagia

Dysphagia is described as difficulty with eating, drinking and swallowing and arises from injury to the neural, sensory, and/or motor systems that underlie swallowing (Robbins et al., 2008). It can affect any of the phases of swallowing and it may be associated with dehydration and malnutrition, lung infection (aspiration pneumonia), poor oral hygiene, decreased immunity, general poor health, immobility and mortality (Humbert, Poletto, Saxon, Kearney & Crujido, 2007). Table 8 summaries the causes of the different types of dysphagia, the swallowing phase affected, swallowing action affected and the complication thereof. Dysphagia caused by a stroke is very common, affecting 27% to 64% (Humbert et al., 2007) of patients. While 50% of stroke patients with neurogenic dysphagia may recover adequate swallowing within two weeks, some will have long term feeding problems and some will die of aspiration pneumonia (Humbert et al., 2007). The incidence of neurogenic dysphagia in stroke may be as high as 78% (Martino et al., 2005). Similarly, chronic, unresolved dysphagia may be present in as many as 92% of head and neck cancer patients (Nguyen et al., 2006). Hence, dysphagia is not only widespread but also disabling and requires various medical and rehabilitative treatments.

Table 8

Dysphagia: Causes, Phases and Motor Action Affected

Types of dysphagia	Causes	Phase of swallowing affected	Motor action of swallowing affected	Swallowing complication
Oropharyngeal dysphagia	Neurogenic causes; Damage to brainstem swallowing centre; stroke, damage to efferent or afferent nerves V, VII, IX, X & XII Mechanical causes; UES dysfunction, decrease in muscle function Obstructive causes; Infections, head and neck malignancies.	Oral preparatory Oral phase	Incomplete lip closure Tension decrease in cheek muscles Range of motion decrease of the lower jaw Decrease in tongue movement	Insufficient pressure generation for bolus propulsion Inadequate bolus manipulation
		Pharyngeal phase	Delayed or no trigger of the swallow reflex Reduction in velopharyngeal	Food entering the pharynx without the four neuromotor events occurring

	Myogenic (muscle contractile disturbances) Psychogenic Age		closure Uni-or bilateral damage pharyngeal peristalsis due to weak constriction Damage to elevation of the larynx Damage to laryngeal adduction Damage to cricopharyngeus muscle	Reflux of bolus into the nasal cavity Residue in pharyngeal recesses Ineffective airway protection, leaving residue on top of airway Bolus residue in pyriform sinuses
Esophageal dysphagia	Mucosal disease Mediastinal disease Neuromuscular disease	Esophageal phase	Decrease in the lumen Obstruction of esophagus by lymph-node swelling Affected smooth muscle in esophagus result with disruptive peristalsis Incomplete relaxation of LES (Achalasia)	Discomfort, heartburn and gastric reflux Peptic strictures Esophageal cancer

Note: Adapted from Marshall, 1985; Broniatowski et al., 1999; Palmer et al., 2000; Richter, 1998, Kirshner, 1989.

2.7. Aspiration and Penetration

Aspiration is defined as food particles entering into the airway below the true vocal folds, whereas penetration is defined as food particles entering the laryngeal vestibule passing the level of the true vocal folds (Logemann, 1992). Clinicians use certain methods to determine aspiration in patients; bedside swallowing assessment, pulse oximetry, cervical auscultation, videofluoroscopy swallow studies (VFSS) and fiberoptic endoscopic swallowing studies (FEES) (Sun et al., 2013). The cough reflex acts as protective mechanism to the airway and forms the basis of the bedside diagnosis of aspiration (Canning, 2007).

It may also occur during aspiration that the respiratory mechanism does not respond with the cough reflex or any audible noted behaviour. This is known as silent aspiration and is missed according to 40-70% of bedside assessments (Daniels, Ballo, Mahoney & Foundar, 2000; Logemann, 1998). To accurately diagnose the occurrence of silent aspiration it is indicated throughout the literature that the preferred instrument for analysis is videofluoroscopy swallow studies (VFSS), also referred to in the literature as a modified barium swallow (Martin-Harris & Jones, 2008). VFSS not only captures bolus flow, but also enables the examiner to identify the presence and timing of swallowing impairment, this enable the examiner to identify physiological causes of the occurrence (Logemann, 1999; Martin-Harris, Logemann, McMahon, Schleicher & Sandidge, 2000).

2.8. Videofluoroscopic Swallow Study (VFSS)

Videofluoroscopic swallow study (VFSS) is also referred to as modified barium swallow (MBS) and is one of the most common tools used in evaluating and managing dysphagia (Logemann, 1998). Videofluoroscopic swallow study enables one to observe the bolus and movement of surrounding swallowing structures. Information on bolus position, speed and timing are generated and this assists in identifying problem areas for treatment purposes (Palmer, 2000).

Swallow imaging procedures have been developed over the last 50 years. Originally cinefluorography was the technique used to define the various elements of the swallow during the pharyngeal phase. The development of video tape recordings made videofluorography possible and became the procedure of choice due to lower radiation exposure (Logemann et al., 1998). Ongoing development of this technique produced VFSS, which is now considered to be the gold standard in assessing swallowing function, and more specifically, HLC movement (Logemann, 1993; Leonard, 2006; Terk, Leder; & Burrell, 2007). Videofluoroscopic swallow study is the most frequently used analytical tool of choice in clinical settings, as it is one of the most important methods to evaluate the presence of aspiration, penetration, hyoid bone movement and duration of a swallow (Van der Kruis, Baijens, Speyer & Zwijnenberg: 2011).

Videofluoroscopic swallow study images and/or analyses have also been used in research studies describing swallowing biomechanics in healthy individuals (Cook et al., 1989; Kendall, McKenzie & Leonard, 2000; Aminpour, Leonard, Fuller, & Belafsky, 2011). Radiation exposure during VFSS is reported to be between 0.2 and 0.85 mSv, depending on the duration of the VFSS (Bonilha et al., 2013) and produces image sequences, as seen in Figure 6, which can be digitized and analysed using various software applications. Such applications enable the analyser to identify important anatomical landmarks of interest, such as the anterior, superior cornu of the hyoid bone, and also to accurately measure movement patterns captured frame-by-frame (Van der Kruis et al., 2011). In our study, VFSS was used to accurately measure differences in the (x, y) positions of the HLC directly from the images generated in order to determine whether a single session of NEMS had any effect on the positioning of the HLC post-stimulation.

A recent systematic review of studies regarding biomechanical analysis in VFSS as a spatial outcome parameter indicated that intervention effects of NMES for hyo-laryngeal movement can be successfully detected by means of VFSS (Van der Kruis et al., 2011). However, no universal standardised software application to analyse hyoid bone displacement exist, this poses problems when using VFSS as an analytical tool for pre- and post-NMES comparisons (Van der Kruis et al., 2011).

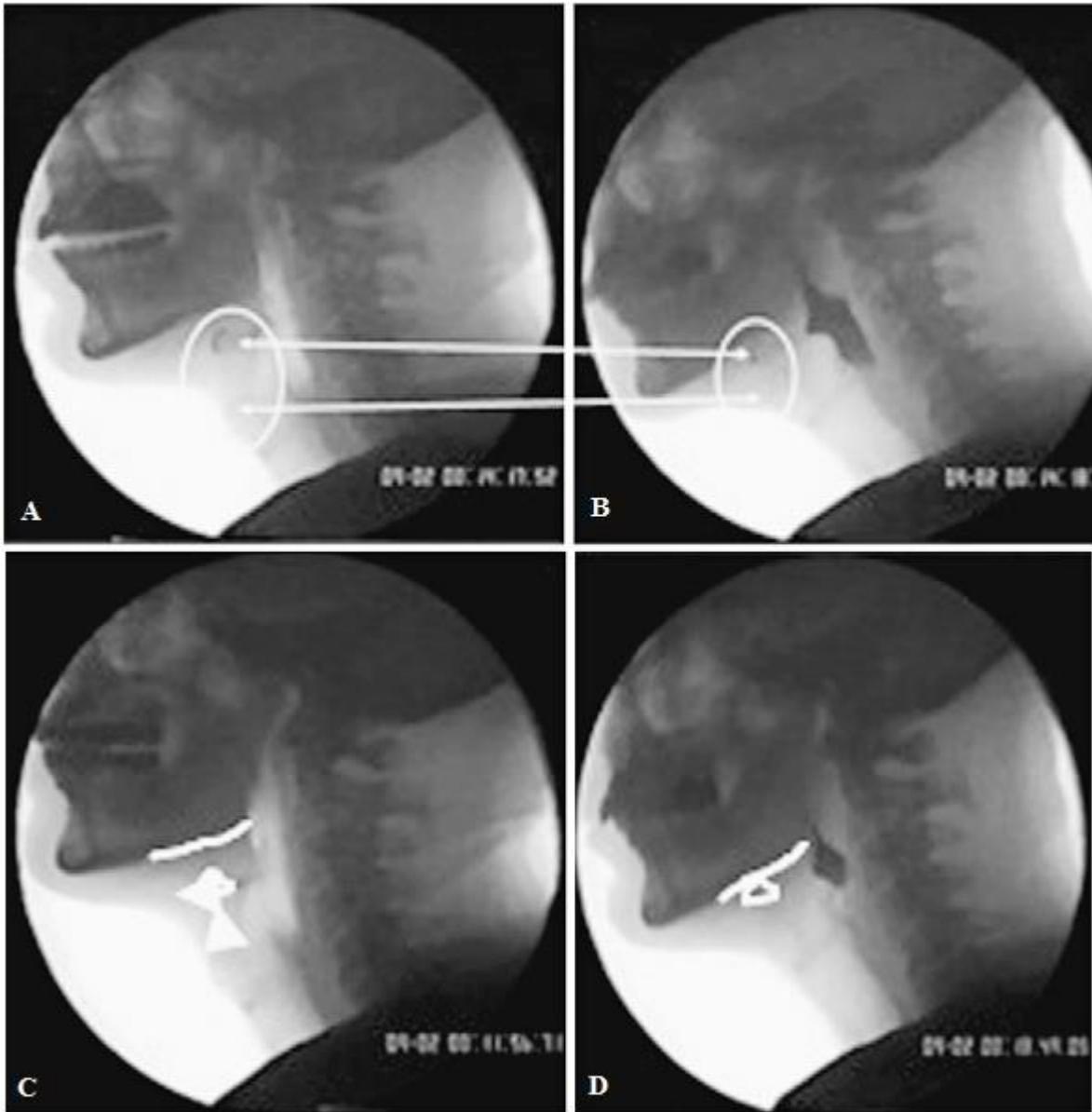


Figure 6. VFSS of the hyo-laryngeal complex. The figure illustrates the elevation and anterior movement of the larynx and hyoid bone. Adapted from “The Videofluorographic Swallowing Study” by B. Martin-Harris and B. Jones, 2008, *Physical Medicine and Rehabilitation Clinics of North America*, 19, 769 – 785p. Copyright 2008 by Elsevier Incorporated.

2.9. Swallowing Rehabilitation Methods

Swallowing therapies are designed to shorten hospitalization and speed up the recovery of impaired swallowing and to reduce the risk of pneumonia. Treatment for dysphagia is given to patients by speech language therapists (SLTs) who focus primarily on compensatory strategies to improve coordination and strength of the swallowing muscles (Odderson, Keaton & McKenna, 1995). Such compensatory strategies include postural adjustments, i.e. head turns and chin tucks, supraglottic swallowing manoeuvres and bolus modifications (textural, volume, pace, thermal, chemical) (Kuhlemeier et al., 2001). There are however certain drawbacks to these compensatory strategies, as they must be implemented with every swallow and produces no lasting physiological change (Davies, 2012). In addition, it may also lead to reduced pleasure when eating (Daniels & Huckabee, 2008; Robbins et al., 2008). These traditional treatment methods may also be problematic and exhausting for patients with cervical spine injuries or increased frailty and leaves clinicians to search for alternative rehabilitation methods (Bauer & Huckabee, 2010). In response to these on-going issues, patient care has continued to evolve from a purely compensatory approach to achieving a more permanent shift in underlying swallowing physiology. Thus, modern rehabilitation methods have been developed and are now available as treatment option (Jayasekeran et al., 2010). Dysphagia rehabilitation aims to strengthen swallowing muscles and can be done manually or by means of electrical stimulation which is applied to the oral and pharyngeal structures. It is also known that the muscles involved in mastication and swallowing do adapt in response to increases in load (Thompson et al., 2001; Vincent et al., 2002). In a review by Robbins et al. (2008) swallowing rehabilitation methods are listed as shown in Table 9 below. In their research they indicate if the treatment method demonstrated behavioural or neural plasticity. Thermal-tactile and electrical stimulation are the only rehabilitation methods demonstrating neural plasticity compared to other methods (Robbins et al., 2008). It is shown that sensory rehabilitation methods applies to all the principles of neural plasticity, but how the principle of time affects this method remains unknown (Robbins et al., 2008) This supports the need for further research involving sensory stimulation methods such as NMES.

Table 9*Dysphagia Rehabilitation Methods*

Sensory rehabilitation methods	
Bolus effect	
Volume	Bolus volume influence swallow biomechanics, timing, duration of the pharyngeal structural movement
Viscosity	Bolus viscosity influence swallow biomechanics, timing, increase duration of laryngeal vestibule closure and UES opening
Thermal, Taste, Tactile	Some changes in swallow biomechanics have been observed, but further research is required
Stimulation	
Thermal-tactile stimulation	It is found that swallowing is changed by all types of sensory stimulation to influence threshold response, reducing the flow of the bolus through the oropharynx. Thermal-tactile and electrical stimulation demonstrated not only behavioural plasticity but neural plasticity.
Electrical stimulation	
Deep pharyngeal neuromuscular stimulation	
Occluding tracheostomy	
Visual feedback	
Compensatory rehabilitation methods	
Chin tuck	Compensatory rehabilitation methods are aimed to improve the individual circumstances to assist swallowing, rather than altering the swallowing mechanism. These techniques are successful with individuals suffering from minimal to mild severity of dysphagia.
Head rotation	
Head tilt	
Head back	
Side lying	
Breath hold	

Bolus consistency	
Motor with swallow rehabilitation methods	
Mendelsohn manoeuvre	These rehabilitation method refers to performing motor exercises along with performing the swallowing action. It is shown to improve swallowing coordination, strength and range of motion as well as behavioural plasticity, but no neural plasticity changes are detected.
Super supraglottic swallow	
Supraglottic swallow	
Effortful swallow	
Tongue hold	
Swallow (frequency)	
Motor without swallow rehabilitation	
Range of motion	Motor rehabilitation without swallow aims to improve range of motion and strength and improving respiratory. It is shown to be effective in treating individuals suffering from severe dysphagia.
Strengthening tongue	
Strengthening-respiratory	
Tongue control	
Shaker exercises	
Lee Silverman Voice Treatment	
Pharyngeal exercises	
Gargling	
Vocal exercises	
Velar elevation	
Airway closure or breathing hold	

Note: Adapted from Robbins et al., 2008; Swallowing and Dysphagia Rehabilitation: Translating Principles of Neural Plasticity Into Clinically Oriented Evidence.

2.10. Neuromuscular Electrical Stimulation

Neuromuscular electrical stimulation is a well-known rehabilitative method in the field of physiotherapy, in assisting in the recovery of motor function (Maffiuletti, 2010). The aim of NMES is to activate specific muscles through stimulation of the intact motor neurons. The primary goal in this is to strengthen weak muscles and to improve recovery of motor control (Wijting & Freed, 2003). Neuromuscular electrical stimulation is aimed at activating non-innervated muscle fibres in the absence of peripheral innervations, as this will retard muscle atrophy and improve local blood flow (Wijting & Freed, 2003). An overview of the types of electrical stimulation in clinical practice are listed in Table 10 below.

Table 10

Types of NMES

Transcutaneous electrical nerve stimulation (TENS)	Uses high frequencies of stimulation for pain relief and also administered at very low frequencies between 2 to 10 Hz. Targeting small afferent sensory fibres to override nerve impulses and minimise pain.
Functional electrical stimulation (FES)	This method of electrical stimulation is most common in the literature and involves coupling electrical stimulation with the task at hand.
Neuromuscular electrical stimulation (NMES)	NMES is used at frequencies between 20 to 50 Hz, causing muscle tetany and twitching and are mainly used for functional rehabilitation purposes.
Electrical stimulation (ES)	Electrical stimulation is used to improve strength, muscle range of motion, edema, atrophy and healing tissue.
Intramuscular electrical stimulation	This method is of invasive nature and makes use of hook electrodes inserted into the muscle to target deeper lying tissue.

Note: Adapted from Doucet et al., 2012; Neuromuscular Electrical Stimulation for Skeletal Muscle Function.

Pharyngeal stimulation is shown to induce functional reorganization leading to improved swallowing performance; this shows a direct relationship between stimulation, cortical excitability and improvement in swallowing function (Fraser et al., 2002). This method of treatment was clinically proven; not only to improve swallowing function, but also to reduce the risk of aspiration and hospitalization times (Jayasekeran et al., 2010; Steele et al., 2011). Functional electrical stimulation (FES) refers to NMES applied to a specific area whilst performing the action which is to be improved. For the purpose of strengthening the underlying muscles NMES is applied transcutaneous or intramuscularly (Clark, Lazarus, Arvedson, Schooling & Frymark, 2009). Transcutaneous electrical stimulation will entail applying surface electrodes to the skin, electrical stimulation travels through the cutaneous tissue to the motor neurons. Whereas intramuscular electrical stimulation entails electrical stimulation applied directly into the muscle via hook electrodes (Hardin et al., 2007).

Typical application of NMES makes use of transcutaneous electrical stimulation, due to its less invasive nature, cost effective, safe and easy way of targeting the motor neurons (Sluka & Walsh, 2003; Clark et al., 2009). Electrical stimulation has been applied since 1997 on dysphagic patients (Jordan, 1997) and was developed in 2002 into portable stimulation devices (Fraser et al., 2002). A lack of knowledge regarding the specific effects on the neurophysiology and biomechanics underlying swallowing still exists. Factors known to determine the effect of NMES have been identified as the frequency, stimulation duration, or stimulation intensity (Heck, Doeltgen & Hackabee, 2012). According to literature not all electrical stimulation has beneficial outcomes. Some may worsen a swallowing disorder in some patients. This is affected by the amount of stimulation and the placement on surface electrodes around the laryngeal region.

Surface electrical stimulation to the laryngeal region cause significant hyoid and laryngeal descent at rest and reduce hyoid and laryngeal peak elevation during swallowing in healthy adults (Ludlow et al., 2007; Nam, Beom, Han & Ryoan, 2013). Contradictory to this, the literature also indicates that intramuscular stimulation of the thyrohyoid and mylohyoid muscles induce laryngeal elevation comparable to 50% of elevation that occurs during swallowing (Burnett et al., 2003). This suggests that deep electrical stimulation to the target area enhances hyo-laryngeal elevation in dysphagia.

A lack of knowledge regarding the specific effects on the neurophysiology and biomechanics underlying swallowing still exists. Only a few clinical controlled trials have compared traditional dysphagia therapy to NMES combined with therapy. One study by Permsirivanich et al. (2009) found no significant difference between traditional dysphagia therapy and NMES, however they found NMES was a superior treatment method. Another by Ludlow (2010), reported no benefit of NMES over traditional therapy in dysphagia post stroke. The study by Humbert, Lokhande, Christopherson, German, and Stone (2012) reported greater improvement in the NMES versus a sham group based on only one of the four outcome measures in dysphagia secondary to head and neck cancer. Therefore, to

date, the evidence suggests only a very limited benefit, if any, of adding NMES to traditional therapy for treatment of dysphagia (Humbert et al., 2012; Bülow, Speyer, Baijens, Woisard, & Ekberg, 2014).

Different electrical stimulation devices have been developed for the purpose of rehabilitation of dysphagia. The VitalStim® Therapy System devices have been FDA approved (FDA 510(k) Summary. No. K070425, 2007) and form the basis for further NMES devices. The VitalStim® Therapy System was approved for the stimulation in the pharyngeal area for the purpose of muscle re-education, but no specific age or population recommendations currently exist. This apparatus makes use of surface electrodes applied to the skin tissue and targets the deeper lying muscles. Similar NMES devices have been FDA approved to date according to the specifications of The VitalStim® Therapy System for example the Guardian Way® and others (FDA 510(k) Summary. No. K120922, 2013). More sophisticated devices such as the Phagenyx® device make use of a catheter to apply direct pharyngeal electrical stimulation (“How Phagenyx Works”, 2014).

The NMES method used in the study was the VitalStim® Therapy System. It is a surface electrical stimulation device, which delivers a low current signal (0.5 – 6.0 mA) to the area of placement through electrodes. These electrodes are attached to the surface of the skin on the anterior neck area of the individual. It is currently in use in South-Africa (Wijting & Freed, 2003).

2.10.1. Neuromuscular Electrical Stimulation Mechanism of Action

The work of Aloisio Luigi Galvani, a scientist from the 18th century, formed the basis of electrophysiology (Piccolino, 2008). Literature has reported on the phenomenon and fundamentals of the physiological action regarding electrical stimulation of the nervous system (Eberstein & Eberstein, 1996). However, for the purpose of this study, to understand this concept and how NMES influences and triggers motor response, we need to understand the way in which motor neurons function. Neurons in the body have conductive properties allowing impulses to be carried along their surfaces.

This is possible due to ionic interaction across plasma membranes in these cells, also referred to as membrane potential. At rest positive charge exist outside the plasma membrane and a negative charge inside the plasma membrane, as shown in Figure 7 (A). A small fluctuation in this resting potential is responsible for the receiving, conducting and transmitting of impulses. Such fluctuations can only occur when ion-specific channels are opened or closed, which allows for either the influx or efflux of ions, as shown in Figure 7 (B&C). The influx of the surrounding sodium and calcium ions causes depolarization of the cell, whereas influx of chloride or potassium efflux causes hyperpolarisation.

The regulation of transmembrane channels is responsible for the plasma membrane permeability of ions in and out of the cell and is triggered by chemical or electrical stimuli. To be triggered on a chemical level it is required for neurotransmitters to bind to the channel. Electrical stimuli can cause the transmembrane potential to reach a critical level, initiating a polarity difference to a point of depolarization threshold, allowing voltage-sensitive ions acting to open voltage gated ion channels for the period of stimulation, causing a polarity change. This allows sodium ions, surrounding the membrane, to move into the cell through voltage gated ion channels, causing polarity change.

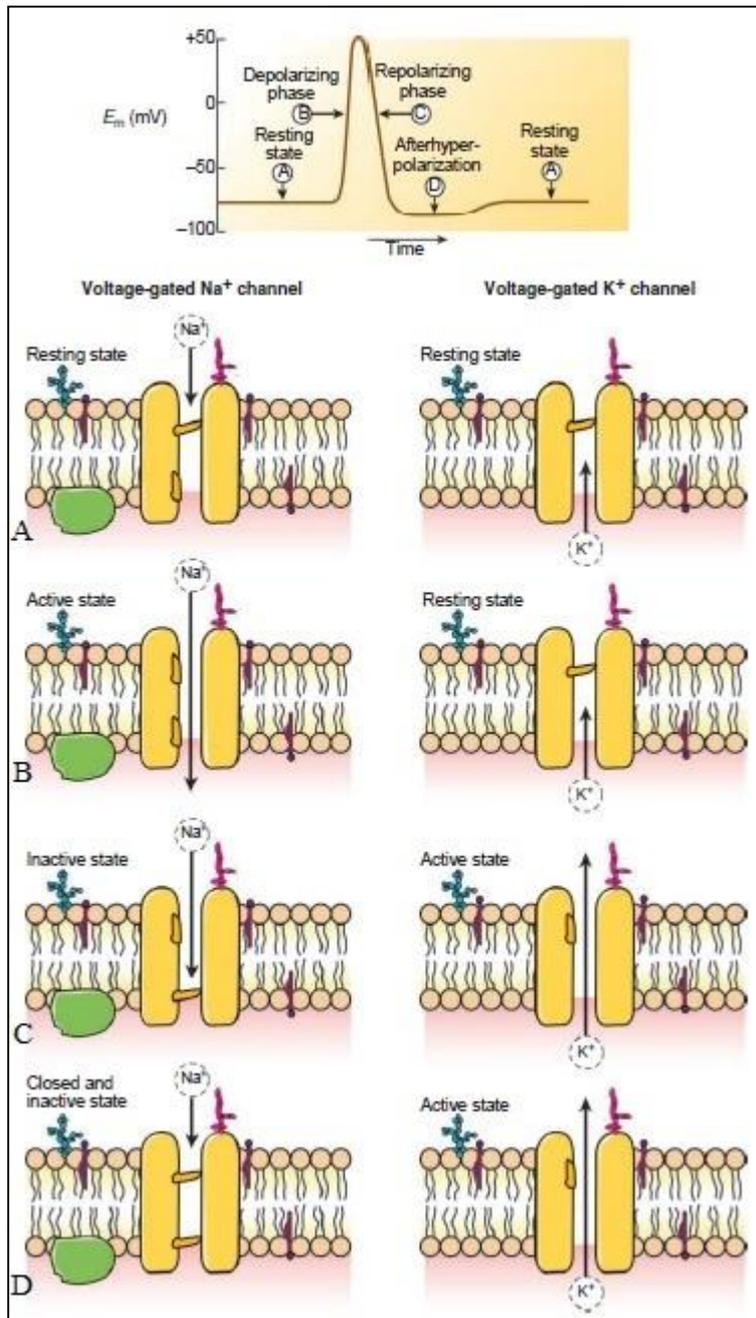


Figure 7. Voltage-gated Channel Activity during the Action Potential. The figure illustrates: **(A)** in the resting state, both sodium- and potassium-gated channels are closed. **(B)** In the depolarizing phase,

sodium channels are activated, whereas potassium channels remain closed. **(C)** In the repolarising phase, sodium channels close by inactivation, and potassium channels are activated. **(D)** In the after hyperpolarisation phase, potassium channels remain activated. As this phase ends, sodium channels reset the activation and inactivation gates to their resting positions and are available to mediate the next cycle of opening. Taken from *Medical Physiology - Principles for Clinical Medicine Fourth Edition*. Copyright 2013 by Lippincott Williams & Wilkins, a Wolters Kluwer business.

This reversal of polarity along membranes causes an action potential, spreading rapidly with constant velocity along the motor axon, as seen in Figure 8. This triggers polarity changes in adjacent nerve cells causing depolarization in both directions of the nerve. Depolarization reaches the muscle at the motor end plate and causes a contraction and depolarization reaches the spinal cord in sensory neurons and result in perceived sensation. Completion of the membrane depolarization triggers other channels to open along the axon and causes potassium ions to flow out the nerve cells. This causes repolarisation and the cell membrane returns to original polarity. When NMES is applied to the tissue area it creates depolarization of the peripheral motor nerve at the motor end plate which will cause a muscle contraction as previously discussed.

The literature shows that the best area for placing the stimulation electrodes is positioned as close to the centre of the target muscle, known as the motor point, due to the fact that the motor axon branches into the muscle and these branches lose their myelinated sheaths at the muscle belly (Standing, 2008). When applying NMES to the muscle, an important factor to take into account is the muscle fibre types since this will affect the muscle recruitment (Rattay, 1999). The literature indicates that this muscle recruitment during rehabilitative swallow therapy is missing, thus leaving the patient deteriorating or with prolonged recovery time (Wijting & Freed, 2003). Disuse atrophy occurs rapidly when type II fibres are left un-recruited during dysphagic conditions. When stimulated with NMES it is important to note that the fibre recruitment pattern is reversed. This means that type II muscle fibres recruit prior to type I muscle fibres. The reason for this is due to the greater number of motor neurons responsible for innervating type II muscle fibres compared to the number of motor neurons responsible for type I muscle fibre innervations. This means that type II motor neurons have a lower depolarization threshold than type I motor neurons, therefore responding sooner to electrical stimulation. This response to NMES is the reason for a positive effect when using NMES as treatment for disuse atrophy and strengthening the affected muscles.

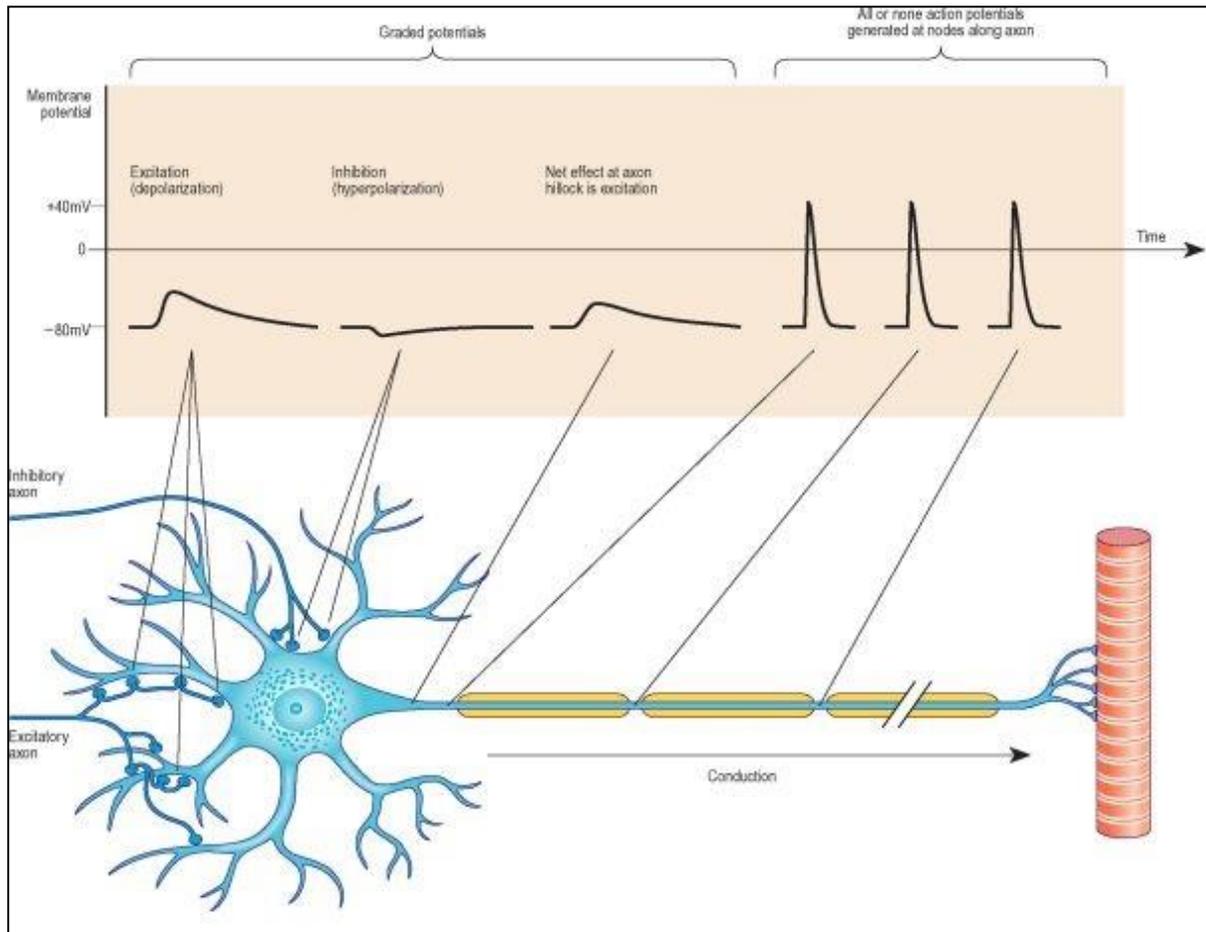


Figure 8. Change in electrical potential of motor neuron. This figure illustrates the changes in electrical potential recorded across a motor neuron at specific points. Taken from Gray's Anatomy The Anatomical Basis of Clinical Practice Fortieth Edition, Copyright 2008 by Elsevier Limited.

2.11. Training Principles

In this section each principle of training as described in the literature will be briefly discussed, these principles of training are important to conceptualise the influencing factors regarding the effect and outcome relationship of any form of training. The goal of training is to achieve peak performance of a specific skill related to a motor action or function (Burkhead et al., 2007). To train for peak performance effectively, we need to follow three principles; overload, specificity and reversibility (Fahey, 1998; Powers & Howley, 2007). The aim is to match the training to the movement demand trained for. The outcome will be influenced by these factors; gender, initial fitness level, genetics and the age of the individual (Korfage et al., 2005; Powers & Howley, 2007, Molfenter & Steele, 2014).

2.11.1. Overload

As described by Powers and Howley (2007) overload refers to the increase of exercise intensity, frequency and duration of above accustomed levels. Overloading of the muscles involved as described by Burkhead et al. (2007) in their research on the 'Shaker Head Lift' exercises showed to affect dysphagia rehabilitation outcomes significantly. When training for endurance, overload would mean to challenge the muscles for longer duration on sub-maximal intensity more frequently. Overloading for strength training would mean to increase the resistance load, performing maximal intensity more frequently. Training for endurance or strength will have different changes on muscular level, and should be considered when training for peak performance. This concept of overload is important to keep in mind when applying resistance loading in dysphagia rehabilitation (Burkhead et al., 2007).

2.11.2. Specificity

Training effect is specific to the type of muscles, muscle action, muscle fibres and metabolic system involved (Powers & Howley, 2007). The adaptations observed on muscular level would be specific to muscle fibre composition of the muscle in relation to the energy system targeted during exercise (Bruton, 2002). Muscles high in type I (slow-oxidative) fibres will improve its oxidative capacity by increase mitochondria, capillary density and oxidative enzymes, whereas muscle adaptations resulting from strength training would be increase neural motor unit recruitment, contractile protein, fibre size (hypertrophy) and force production.

Training needs to be specific to ensure the correct outcome as desired for improving performance. It is important to note for this study the mylohyoid, anterior belly digastric, sterno- and omohyoid muscles are most likely to be stimulated (Wijting & Freed, 2003). Deeper lying muscle include; geniohyoid, thyrohyoid; middle pharyngeal constrictors, which might possibly be stimulated. On average swallowing muscles consist out of equal amounts of slow and fast twitch fibres, however it is found that these small muscles have much higher levels of hybrid (Type IIX) muscles than other skeletal muscles in the human body (Mu & Sanders, 2002; Mu, Liancai, Su, Wang, Han & Sanders, 2004; Korfage et al., 2005).

2.11.3. Reversibility (detraining)

This principle shows the temporary nature of adaptations on muscular level. Discontinuing training will cause the adaptations to return to baseline. This phenomenon is also known as detraining and is specific to the type of adaptation that had occurred in the muscle (Bruton, 2002). In endurance adaptations rapid decrease of muscle plasma volume and hemoglobin concentration can be observed within twelve days and thereafter mitochondrial changes occur (Coyle, Hemmert & Coggan, 1986; Coyle, Hopper & Coggan, 1990). The literature has shown that within one week of detraining 50 % of

mitochondria gained in five weeks of endurance training is lost (Powers & Howley, 2007). Strength gains are shown to rapidly decrease after four weeks of detraining (Mujika & Padilla, 2001).

2.11.4. Influence of Gender

Literature indicates that women and men have similar response to training, thus general physiological approach to training remains uniform (Powers & Howley, 2007). However training should be individualized and volume and intensity should be prescribed according to level of fitness, as this varies from individual to individual (Wilmore & Costill, 1994).

2.11.5. Initial Fitness Level

Initial fitness level plays a role in the amount of improvement that will be observed during training. This means that an untrained individual will show greater increases compared to an individual which is trained (Powers & Howley, 2007). The individual's current swallowing performance needs and past training history needs to be taken into account when starting with any training regime (Wilmore & Costill, 1994).

2.11.6. Genetics

Genetics determine how the individual responds to training (Wilmore & Costill, 1994). If an individual genetically determined with high levels of type I muscle fibres, train for an endurance specific muscle action. He would achieve higher levels of muscle endurance performance for this action than an individual genetically determined with less type I fibre (Korfage et al., 2005). This means that some individuals will be better swallowers than others and be less prone to swallowing disorders later in their lives.

2.11.7. Ageing

Normal ageing of the body result in several muscular changes. Literature indicate a decrease in muscle mass and strength is found with natural aging, however this phenomenon is multi-factorial but according to Borges & Essen (1989) the major reason for this is a decrease of type II muscle fibres. This might be the reason for dysphagia due to normal aging, keeping in mind that the oropharyngeal muscles consist predominantly out of type II muscle fibres (Burkhead et al., 2007). Burkhead et al. (2007) also indicate that hormonal imbalances and decrease in motor units contribute to the prevalence of dysphagia seen with natural ageing.

2.12. Rationale of the Study

When the literature regarding dysphagia is reviewed, major areas of concern are revealed. Dysphagia is predominantly known to occur with the elderly population and the majority of research focuses on the affected population of 50 years and older (Logeman et al., 1997; Shaker et al., 2002; Ludlow et al., 2007). This leaves the field of dysphagia rehabilitation with no normative data on young and healthy individuals as reference point to work from. Thus, in this study, we decided to use healthy individuals to control for neuromuscular changes involved with natural aging, as pointed out above. It is evident that the literature encourages research in the field of modern methods of dysphagia rehabilitation (Burkhead et al., 2007; Robbins et al., 2007; Shaker et al., 1997). This study aims to address such a gap in its focus on the effect of NMES on the HLC. The reason for the focus on this specific biomechanical complex is due to its important function in healthy swallowing, identified by its distinctive movement pattern as described the literature (Chi-Fishman & Sonies, 2002). Due to insufficient understanding and research around the effects of rehabilitation exercises on the muscles, modern methods of treating dysphagia such as NMES is even more neglected in the literature. In recent research conducted on patients that had an acute stroke it was found that NMES combined with traditional dysphagia therapy proved to be more effective than traditional dysphagia therapy alone (Kushner, Peters, Eroglu, Perless-Carroll & Johnson-Greene, 2013). However we do know that muscles involved in deglutition do adapt in response to rehabilitation exercises (Fujiu & Logemann, 1996; Burkhead et al., 2007). Muscle strength training, such as tongue exercises (Kahrilas et al., 1993; Logemann & Kahrilas, 1990) and the Shaker exercise, aims to improve suprahyoid muscle strength, anteroposterior diameter of the UES and maximal anterior laryngeal excursion increases significantly (Shaker et al., 2002). Data gathering on the effects of direct pharyngeal NMES on the 'normal'/healthy individual will generate normative data which does not currently exist. This encourages further research in NMES as a treatment modality for dysphagia, demonstrate the lasting effect of NMES therapy and contribute toward development of rehabilitation treatment methods.

2.13. Summary

Conceptualizing muscle structure, composition and action in the human body is important for understanding the effect that any proposed treatment will have on the function thereof. Exercise physiology is also important to consider when aiming for a sustainable improvement in any muscular complex responsible for a specific function in the human body. These factors equip us to understand and guide us towards developing effective rehabilitation treatments for such specific function as swallowing.

CHAPTER 3: MATERIALS AND METHODS

The following section gives an overview of the research design, participant selection criteria and procedures used in this study. Furthermore, the methods and procedures for both the data collection and methods of analyses are described.

3.1. Participants

The study aimed to include thirty young healthy participants consisting of 15 females and 15 males, between the ages of 18-25 years as determined by a qualified SLT to have normal swallowing ability. Prior to any data collection, ethical clearance was obtained from the Institutional Review Board (IRB) from the Health Research Ethics Committee (Stellenbosch University, South Africa) as set out in Appendix A.

The well-being of the participants took precedence over all other interest and the study conformed to general accepted scientific principles. Appropriate caution was taken when participants were exposed to radiation and NMES, as the research procedures were conducted by qualified radiographers and radiologists. All participants were also supervised by a competent and appropriately qualified physician or other health care professional (including qualified SLT and radiologist).

The study acknowledged the risks involved when conducting VFSS and NMES procedures (exposure to radiation and electrical stimulation). It was therefore conducted by a qualified SLT, Radiographer and Radiologist. Standard clinical safety procedures were followed during all VFSS and radiation exposure was kept to the minimum according to the principle of 'ALARA' (as low as reasonable achievable) as stipulated by the Nuclear Regulatory Commission Regulations (2013).

Similarly the NMES procedure was conducted by the primary investigator, who was trained in the certified VitalStim® Therapy System. Strict safety guidelines, as prescribed by the manufacturing company, were followed when participants were stimulated. On the basis of numerous reviews conducted by the FDA, the VitalStim® Therapy System has been cleared to be safe and efficacious in the treatment of dysphagia (Wijting & Freed, 2003).

Each volunteer was required to read through the informed consent form (ICF) explaining what their role and responsibilities would be in the research study, as shown in Appendix B. All participants were encouraged to ask questions to obtain full clarity and understanding of all aspects of the study, prior to giving their consent. Each page of the document was initialled and signed in full by the volunteer, primary investigator and a witness. Participants were then allocated a unique number to be used throughout the study in order to reserve each participant's right for participation confidentiality. All participants had the right to withdraw from the study at any time, as participation was of a voluntary nature.

Data was stored and password protected on DVD and a personal computer. This allowed for convenient retrieval of data in the event of loss of data and/or corruption thereof. Health insurance portability and accountability guidelines were followed to maintain and protect the privacy of protected health information of all participants.

3.2. Research Design

The study followed a non-experimental, pre- and post- study design. Non-experimental study designs are defined by Chatburn (2011) as a design that does not directly manipulate or control an independent variable with the main activity being observation. Furthermore, the purpose of a non-experimental study design is not to isolate cause and effect relationships. Non-experimental studies collect data prospectively, thus they do not attempt to exert rigid influences over the design features of the studies. Pre-test/post-test study designs are defined by Polgar and Thomas (2013) as a type of study in which measurements of the groups are taken both prior to and following an intervention. This allows the direct comparison of pre-intervention and post-intervention results for individual subjects and groups of subjects. A pre-test/post-test study design was chosen as it would best answer the question of where change needed to be measured or observed due to an intervention. This design also allowed the participants to act as their own controls.

3.3. Sampling Processes and Procedures

This section describes the processes and procedures that were followed to advertise and recruit volunteers for the study. Participants were recruited and selected according to the sampling methods and included or excluded according to set out criteria as discussed in this section.

3.3.1. Sampling Method

The sampling method was random, convenient and purposive. Randomization was necessary to achieve unbiased comparisons of data regarding pre- and post- intervention (Eccles, Grimshaw, Campbell & Ramsay, 2003). Random allocation of participants to an independent SLT was done by entering participants into a random numbers table on a computer as they applied for participation in the study.

Stellenbosch University Medical Campus (SUMC) was used as location for the recruitment of participants and also for data collection, as it was appropriate and convenient for both the researcher and the participants. SUMC is situated next to Tygerberg Academic Hospital (TAH) which played an integral role in the data collection process and is a familiar institution to most students that enrol at SUMC. According to Brink, Vander Walt and Van Rensburg (2006) “convenience sampling is also referred to as ‘accidental’ or ‘availability sampling’, as it involves the choice of readily available subjects or objects for the study” (2006:132). Brink et al. (2006) also advocated that purposive

sampling enables the selection of data sources based on knowledge of the phenomena being studied. However the disadvantages are the potential for sampling bias, the use of samples that do not represent the population and the limited generalizability of the results.

The study made use of purposive sampling, as respondents were selected according to the selection criteria. Purposive sampling is a form of non-probability sampling, where the researchers select the respondents (Polit & Hungler, 1999).

3.3.2. Recruitment Process

The participant recruitment process was as follows:

- Study posters were placed on all the notice boards at SUMC in order to recruit interested candidates to volunteer to participate in the study. The posters contained a brief description of the study, the inclusion and exclusion criteria, as well as the contact information of the researcher as illustrated in Appendix C.
- Volunteers were expected to contact the primary investigator telephonically or via e-mail and schedule a convenient time in order to enrol into the study.
- Each volunteer received a detailed ICF as illustrated in Appendix B.
- All volunteers, aged between 18 and 25, had to undergo a swallowing screening after which the results of the screening, as well as their age and gender was used to randomly and purposively select 30 (15 male and 15 female) healthy study participants.
- Each participant was assigned a unique number to keep their participation confidential and anonymous throughout the study.
- Participants were then asked to book convenient times to conduct the baseline VFSS, NMES session and the follow-up VFSS.

3.3.3. Inclusion Criteria

The study population consisted of 30 healthy young adults and was selected according to the following criteria:

- All participants had to be between the ages of 18 to 25 years of age.
- All participants had to pass a basic swallowing screening and present with a normal swallow.
- Adherence to clinical procedures, as explained by qualified staff.

3.3.4. Exclusion Criteria

Individuals who applied to participate in the proposed study were excluded as part of the study population based on the following exclusion criteria:

- If the volunteer did not fall within the age criteria of 18 to 25 years of age
- If the volunteer revealed any history of swallowing impairment or presented any swallowing difficulties during the swallowing screening.
- If the volunteer had any history of surgery or injury to any of the muscles that affect swallowing.
- If the volunteer had any history of jaw, spinal cord and/or pharyngeal diseases.
- If the volunteer was diagnosed with any neurological or musculoskeletal disorders.

3.3.5. Study Cohort

A total of 33 individuals volunteered for the study, out of which 3 individuals did not meet the inclusion criteria and had to be excluded. Out of which one participant were excluded due to falling outside the target age criteria, the other two participants notified that they have personal commitments to fulfil during the study period.

The remaining 30 participants were enrolled for the study and consisted of 17 females and 13 males. All of them completed the ICF in full and underwent the swallowing screening procedure. Out of these 30 participants 7 had dropped out during the study due to personal commitments. The final study population thus consisted of a total of 22 participants which consisted of 12 females and 10 males. In Table 11 recent studies performed on healthy volunteers are summarized, thereby illustrating the population sizes, various NMES experimentations, outcome measures and results found.

Table 11*NMES Research on Healthy Volunteers*

Researcher	Participants	Method	Outcome Measures	Results
Fowler et al., 2009	20 healthy (10 male, 10 female)	60 min VitalStim® NMES		Measurable changes in voice parameters
Park et al., 2009	16 healthy	NMES intensity was increased until noticeable hyoid depression occurred, 10 x 20 minute sessions over 2 weeks	Electromyographic recordings (EMG) activity of hyoid excursion during swallowing, taken before, immediately after and 2 weeks post intervention.	NMES caused significant increase in hyoid excursion post intervention, but did not last for 2 weeks
Oh et al., 2011	18 elderly, 10 young healthy	Received NMES 1 hour per day for 5 days per week for 2 weeks. VFSS was done at baseline and after last NMES session.	Pharyngeal transit time measured through VFSS and Functional Dysphagia scale through observation	Peak transit times increased significantly after NMES, and swallowing ability improved in the elderly.
Heck et al., 2012	20 healthy (10 male, 10 female)	4 seconds VitalStim® NMES, timed for 60 volitional swallows, intervals of 1 swallow per every 30 seconds	Manometric measures of peak pressure and duration of pressures	Effortful swallows generated greater peak pharyngeal pressure; effect lasted for only 1 hour.

3.4. Data Collection Procedures

Permission from the Chief Executive Officer of the TAH was obtained to conduct the data collection in TAH, by making use of their qualified staff and specialized equipment. The data collection process was conducted over a period of three days as illustrated in Table 12. All procedures involved in the study were explained in detail to each volunteer. They were then required to complete the relevant informed consent forms prior to participating in the study. Once a volunteer gave full consent to participate in the study a baseline swallowing screening was conducted. After the study population had been determined according to the inclusion and exclusion criteria, a VFSS was completed with each participant to determine baseline measurements of HLC movement. Each participant then received a once-off NMES session prior to completing a second VFSS to determine changes in measurements of HLC movement.

Table 12

Data Collection Process

	Procedure	Location	Duration
Day 1	Baseline Swallowing Assessment	Tygerberg Student Centre, 1 st Floor, Room 1004	10min
Day 2	VFSS 1 (Baseline Measurement) <ul style="list-style-type: none"> • Single barium swallow exam 	Radiology Department, 4 th Floor, Main reception waiting area, TAH	6 min
Day 3	NMES <ul style="list-style-type: none"> • 14 minute VitalStim® session 	Radiology Department, 4 th Floor, Fluoroscopy waiting area, TAH	20 min
	NORMAL DAILY ACTIVITIES		06:00 – 14:00
	VFSS 2 (Repeated Measurement) <ul style="list-style-type: none"> • Single barium swallow exam • Variable time elapsed per participant between NMES and repeated measurement (0 – 480 minutes post-NMES) 	Radiology Department, 4 th Floor, Main reception waiting area, TAH	6 min

3.4.1. Swallow Screening

3.4.1.1. Procedure

The swallowing screening was conducted by a qualified SLT and consisted of a series of questions, tongue manoeuvres as shown in Appendix D and a water swallow test. The procedure took approximately five minutes to complete.

3.4.1.2. Method and Instrument

Each participant had to sit upright facing the SLT maintaining chin at 90 degrees to neck position. The SLT questioned participants about history of swallowing difficulty and assessed the participant's level of consciousness, sitting tolerance and head control. The SLT instructed participants to perform water swallows to observe swallowing performance and visible signs of aspiration. The SLT observed for any diminished trigeminal-, facial-, glossopharyngeal-, vagus- and hypoglossal nerve function. Participants received a score, as shown in Appendix D, for each category which then indicated the presence or absence of any swallowing difficulty. A single skin fold measurement was taken on the laryngeal area with a Lange™ skin fold calliper to record neck adipose tissue measurements.

3.4.2. Videofluoroscopic Swallow Study (VFSS)

3.4.2.1. Procedure

A 22% barium powder suspension was mixed in five millilitres of water in order to capture the swallowing sequence and contrast-impregnated bolus in real-time as videoradiographic images. Staff from the TAH Division of Radiodiagnosis assisted in conducting each barium swallowing exam. Participants had to book convenient times within the TAH availability on two consecutive days to perform two barium swallowing exams. The first barium swallowing exam was pre-NMES and the second barium swallowing exam was post-NMES.

3.4.2.2. Method and Instruments

VFSS is known in the literature as the preferred method by clinicians to visually assess the swallowing physiology of patients (Martin-Harris & Jones, 2008). The Meccall S.R.L. Superix 164, as illustrated in Figure 9 and 10, was used to capture real-time sequential radiographic images.



Figure 9. Mecall S.R.L Superix 164. The figure illustrates the platform and videofluoroscopic instrument used to capture sequential radiographic images.



Figure 10. Mecall S.R.L. Superix 164. The figure illustrates the videofluoroscopic instruments control panel.

An important calibration setting to standardize throughout VFSS is the zoom setting. The Meccall S.R.L. Superix 164 device has four zoom levels; normal-, 1-, 2- and 3-zoom. All radiographic images were captured in the normal zoom setting for the purpose of standardizing all radiographic images and scaling images from pixels to metric measurements, as provided by the manufacturer and illustrated in Table 13.

Table 13

Radiographic Image Zoom Level to Distance Ratio.

Zoom (level)	Pixels	Distance (cm)
N	30	1
1	39	1
2	53	1
3	72	1

The participants were instructed to wear plain comfortable clothing with no reflective properties and to arrive 10 minutes prior to their exam at the main radiology reception area of TAH. Each participant was instructed to stand on the platform of the videofluoroscopic device, facing sideways with their chin 90 degrees to the neck. The participants were then instructed to place the barium solution in the oral cavity and to keep the bolus there until instructed to swallow. The radiologist calibrated the videofluoroscopic device according to normal zoom, acceptable contrast and lateral laryngeal area of the neck, in order to clearly indicate the movement of the HLC as described in Appendix E. The radiologist then instructed the participants to keep their posture and swallow the bolus with one swallow while capturing sequential radiographic images.

Each exam generated between 60 - 250 radiographic still images and was then captured in sequence on the picture archiving and communication system (PACS) for later examination by the primary investigator. These images were captured in digital format known in the medical field as 'Digital Imaging and Communications in Medicine' (DICOM) as illustrated in Figure 11.

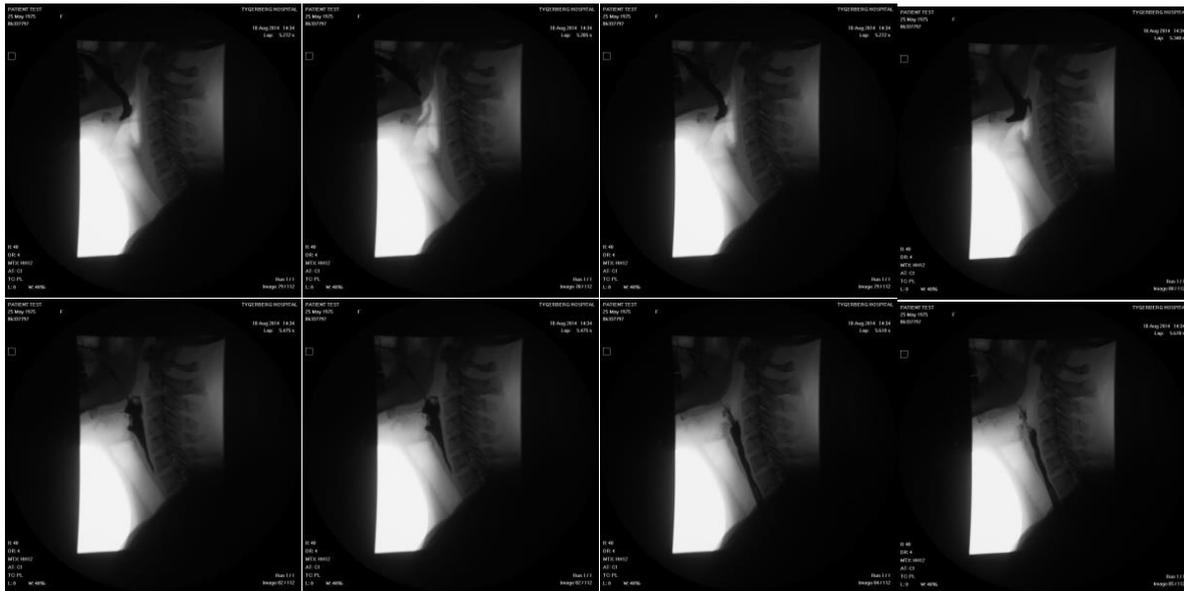


Figure 11. VFSS digital images. The figure illustrates the lateral radiographic images captured during VFSS to observe the movement of the hyo-laryngeal complex during a single swallow of barium solution. Copyright 2011 by Springer Science-Business Media.

3.4.3. Neuromuscular Electrical Stimulation (NMES)

3.4.3.1. Procedures

NMES makes use of pulsed electrical current applied to muscle, nerve or neuromuscular junctions improving strength, stamina and reaction time. However there are different protocols for the application of NMES in the field of swallowing rehabilitation (Freed et al., 2001; Fraser et al., 2002; Power et al., 2004; Doeltgen, Dalrymple-Alford, Ridding, & Huckabee, 2010). This study adapted its method from the works of Freed et al. (2001) and Doeltgen et al. (2010). The VitalStim® Therapy System was used to deliver NMES to healthy individuals as it is FDA approved and currently widely used in clinical practice (Shaw et al., 2007). Electrode placement 3b was selected, due to the fact that this placement causes greatest resistance to the HLC (Humbert, 2006). Due to time limitations NMES was administered as a once-off 14 minute session after maximal tolerable stimulation threshold was obtained: the instrument was on loan for the study and all participants had to undergo the stimulation protocol on the same day. The 14 minutes allocated per subject was calculated in order to accommodate all participants in the same day followed by the VFSS as arranged with the radiologists of the hospital.

3.4.3.2. Method and Instruments

Each participant had to book a time to conduct their NMES session 20 minutes prior to their follow-up VFSS. Each male participant was instructed to shave at least 6 hours prior to receiving NMES as this might have been sensitive to electrical stimulation. Shaving the area of stimulation helped to ensure good surface contact for optimal conductivity. The area of electrode placement on the skin was cleaned with alcohol wipes. The electrodes were placed carefully in position as illustrated in Figure 12 and described in Appendix F.

The VitalStim® electrodes comprised of bi-directional electrodes, thus two pairs of electrodes connected to a lead wire to the output of the VitalStim® Therapy System switching network. This allowed for independent electrical stimulation, or a series thereof, being delivered to each electrode, as illustrated in Figure 12. Detailed specifications of the VitalStim® Therapy System are provided in Appendix G. The electrodes were positioned horizontally on the tissue of the pharyngeal region of each participant as illustrated in Figure 12.

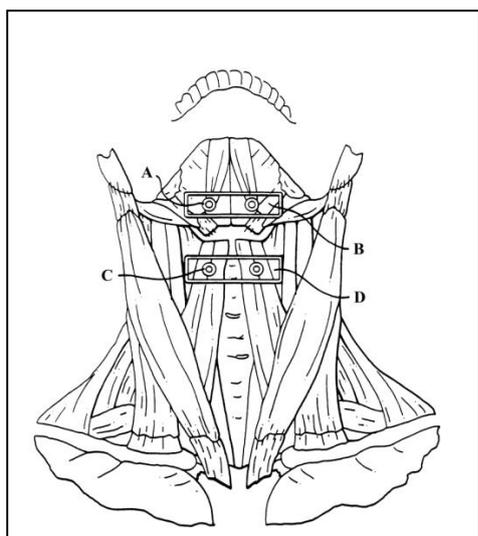


Figure 12. Electrode Placement. This figure illustrates the electrode arrays and their positioning (Wijting & Freed, 2003).

Electrodes A and B is known as one electrode array or channel 1, electrodes C and D is known as the second electrode array or channel 2. Electrodes A and B were placed at or slightly above the hyoid notch on either side of the midline of the pharyngeal region approximately 8 centimeter apart. Electrodes C and D were placed on the thyroid membrane on either side of the midline of the pharyngeal region, approximately 8 centimeters apart, overlying the sternothyroid and thyrohyoid muscles as illustrated in Figure 12. Figure 13 illustrates the portable NMES VitalStim® Therapy System used in the study.



Figure 13. The VitalStim® Therapy System. The figure illustrates the VitalStim® portable NMES unit with two channel electrode arrays. From the VitalStim® Training Manual. Retrieved from <http://www.vitalstimtherapy.com>.

Each participant was instructed to sit in an upright position, face forward and maintain a 90 degree to neck posture. The participant was instructed on the tingle and grabbing sensation of the NMES device. If any pain or discomfort occurred the procedure was stopped immediately on the request of the participant.

The maximal tolerable NMES threshold for each participant was determined prior the 14 minute time locked NMES session as illustrated in Appendix H. During the process of determining the maximal tolerable NMES threshold the electrical stimulation commenced from 0mA and increased every 5 seconds with 0.5 mA. The participant was instructed to indicate when a tingle sensation was felt, then when a grabbing sensation occurred. At the onset of a grabbing sensation the participant was requested to indicate whether this intensity would be tolerable for 14 minutes. The intensity was lowered with increments of 0.5 mA until comfortable level was achieved.

During the NMES session the participant was closely monitored for dizziness, nausea or any tingling sensations at the posterior part of the tongue. These symptoms would indicate incorrect stimulation or stimulation of the carotid sinuses (Wijting & Freed, 2003). According to these symptoms the NMES intensity and electrode placement was adjusted as necessary or the NMES session was restarted.

3.4.4. Data Capturing

3.4.4.1. Procedure

The picture archiving and communication system, as previously described, is the imaging technology in the medical field for various medical imaging modalities. For this study it allowed for the storage and transfer of digital images across its network for convenient access of patient information. This software was convenient for the retrieval of stored images on PACS and enabled the researcher to access the images and import into the Phillips iSite PACS software which was used in this study to scale and measure each two-dimensional linear measurement from the lateral view of the radiographic image of importance.

3.4.4.2. Method and Instruments

Phillips iSite PACS 4.1 software made it possible to identify and analyse hyoid excursion. This was accomplished through a coordinate system commonly used in the literature for standardizing measurements throughout various individuals (Zu, Yang & Perlman, 2011) as illustrated in Figure 14.

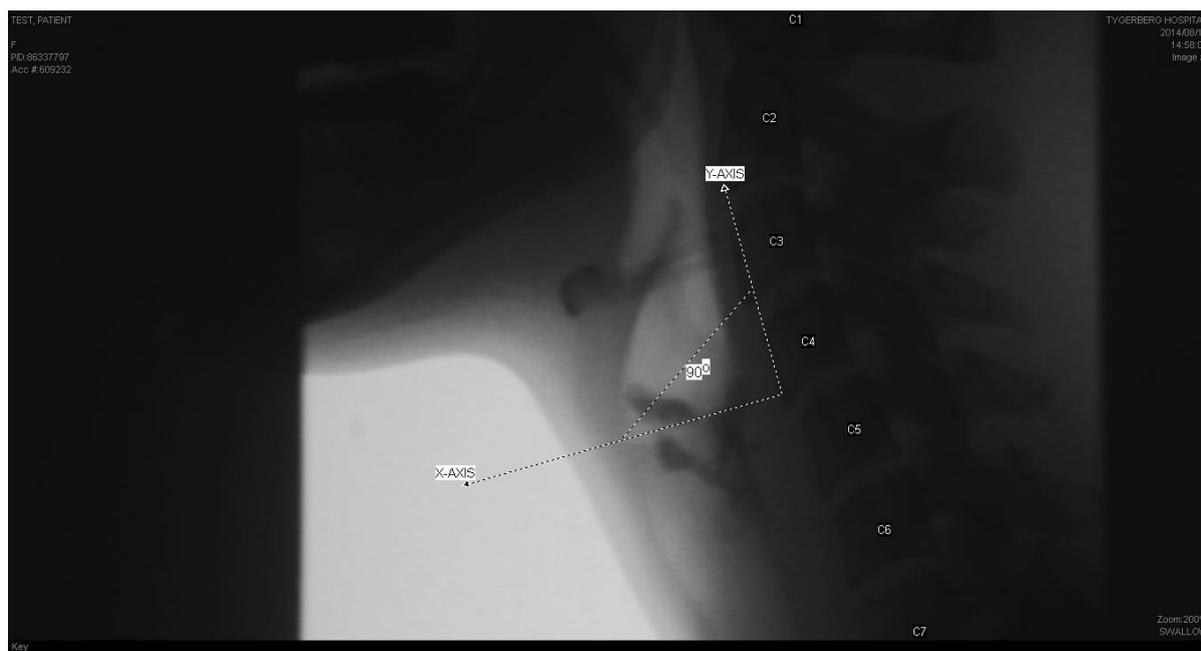


Figure 14. Two-dimensional Lateral Radiographic Image. This Figure illustrates the coordinate system used to do the linear measurements.

The coordinate system is established through identifying the most anterior-inferior point of the second and fourth cervical vertebrae (C2 –C4). Connecting these points forms the y-axis of the coordinate system. The x-axis is determined by extending a horizontal line perpendicular to the y-axis. Once the y and x-axes are determined for each participant x-coordinates (A) and y-coordinates (B) were measured on three key frames of interest. These frames of interest identified as the position where the

hyoid bone is at rest position, most anterior-superior position (hyoid elevation) and when the hyoid bone returned to rest position (hyoid decent) of the swallow. Measurements were taken from the x-axis to the most anterior-superior point of the body of the hyoid bone (A) and from the y-axis to the most anterior-superior point of the body of the hyoid bone (B) as illustrated in Figures 15, 16 and 17.

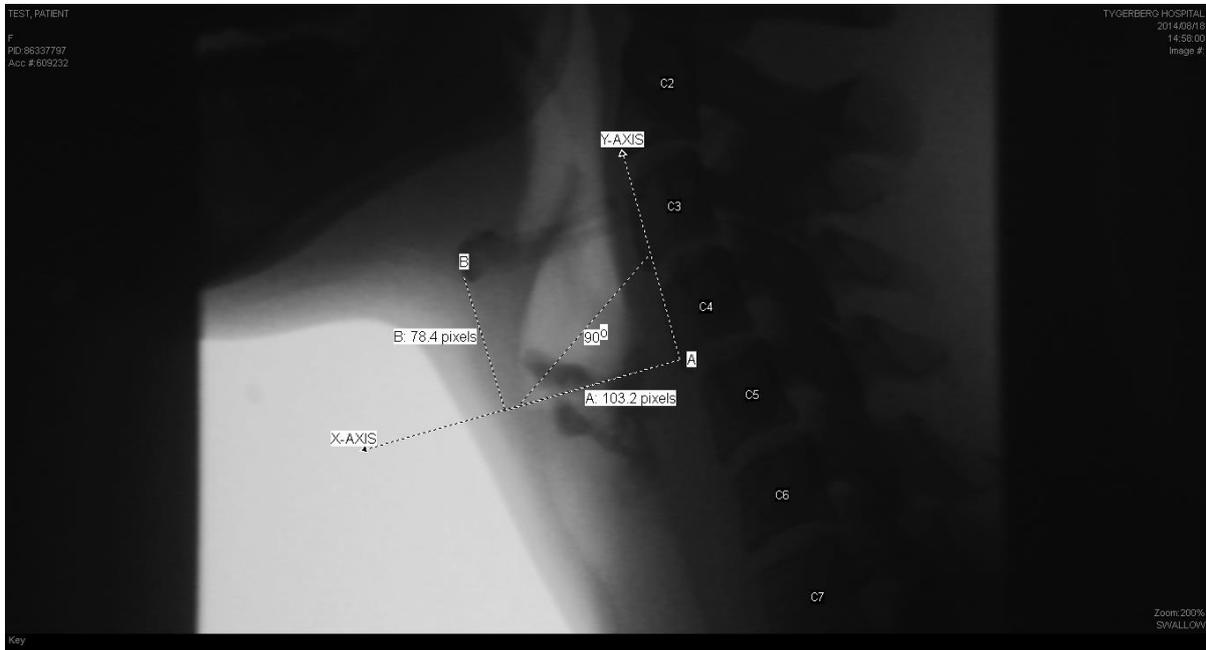


Figure 15. Hyoid Bone At Rest. The figure illustrates the horizontal and vertical measurements of the hyoid bone at rest.

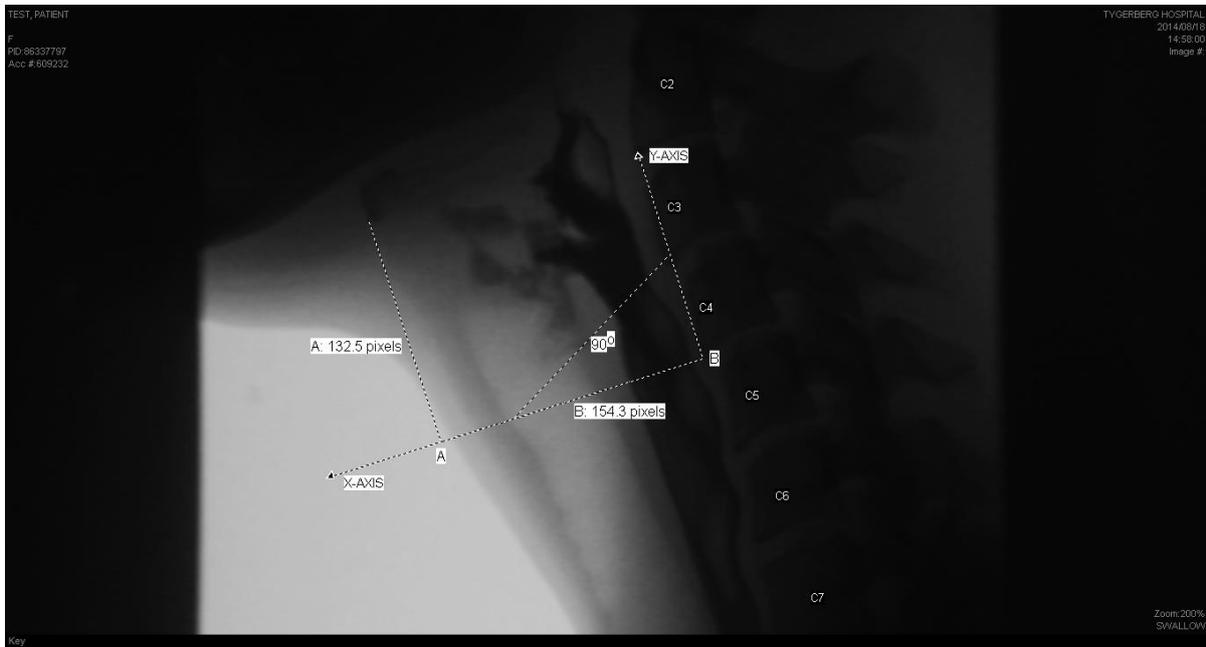


Figure 16. Hyoid Bone At Elevation. The figure illustrates the vertical and horizontal measurements at most anterior-superior position of the hyoid bone.

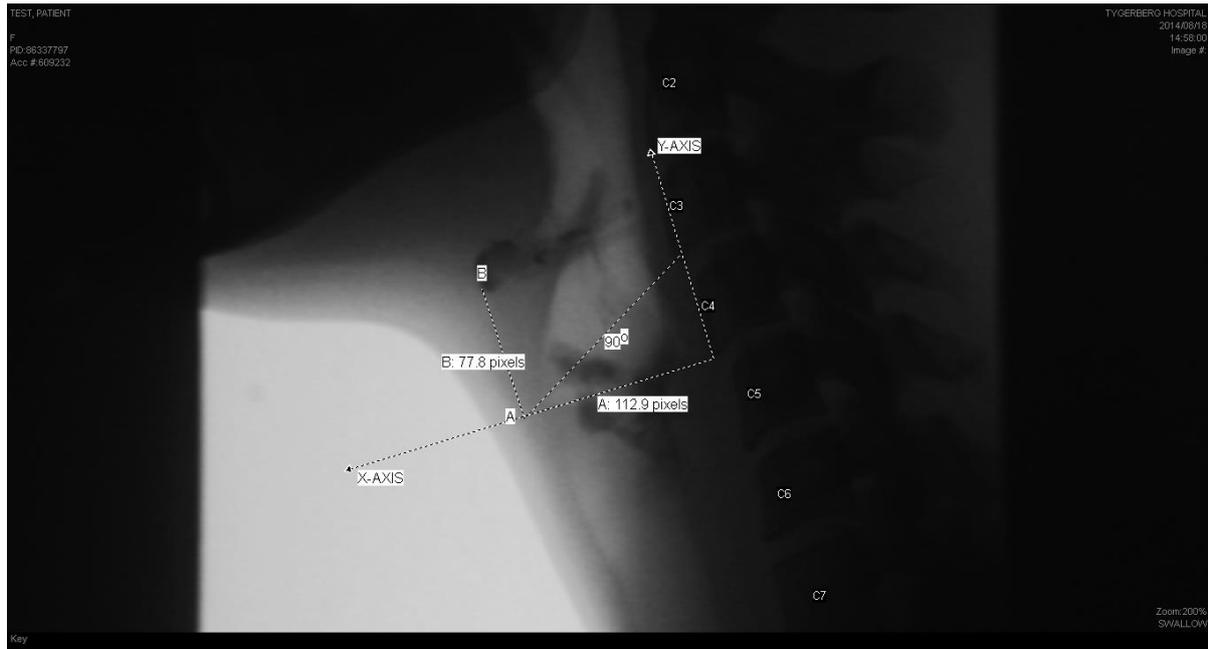


Figure 17. Hyoid Bone At Decent. The figure illustrates the vertical and horizontal measurements at hyoid decent position.

These measurements were repeated on each key frame identified by the primary investigator and verified by a qualified SLT with extensive experience in VFSS. The same measurements were repeated at the first swallowing exam (baseline pre-NMES) and the second swallowing exam (repeated measure post-NMES). These sets of measurements were then used in an analysis of variance to determine if a statistical significant change exists between the first swallow exam and follow-up exam.

3.5. Data Analysis Procedures

3.5.1. Blinding

Raw data obtained from each VFSS in the form of radiographic images for each participant was generated randomly by the TAH registrar allocating a unique patient number to each participant in order to achieve blinding of the primary investigator. The primary investigator identified four frames of interest from each VFSS for measuring purposes. These four frames of interest as discussed previously were then cross-validated by an experienced SLT trained in VFSS. After cross-validation corrections were made and linear measurements were prepared for statistical analysis by the primary investigator.

3.5.2. Statistical Methods

Three sets of data measurements, taken pre- and post-NMES were obtained by means of VFSS and were included for statistical analysis. The null hypothesis was set at that NMES had no effect on the three variables pre- and post-NMES. The mean values were calculated for anterior hyoid movement, superior hyoid movement and hyoid decent at pre- and post-NMES. Initial analysis used a test of analysis of variance (ANOVA) including means of all six pairs of measurement for analysis over the full-duration of the study, pre- and post-NMES combined. Follow-up ANOVA was calculated to compare the means of the three data sets pre- to post-NMES. Following the latter test post hoc testing were needed and the appropriate post hoc tests were performed. A paired samples T-test were required to test significant factors revealed in ANOVA tests. To test for the detraining effect and reversibility of the NMES effect a follow-up ANOVA was done which included a detraining and a non-detraining group. Consultations were done with a biostatistician, Ms. Tonya Esterhuizen, at the Centre for Evidence Based Health Care on SUMC. These consults assisted in the analysis of the raw data, discussion and reporting thereof.

Statistical analysis were performed by SPSS statistics package (IBM SPSS Statistics Version 20). Baseline measurements of hyo-laryngeal movement pattern in young healthy individuals were established through linear measurements by means of a coordinated system. A single factor repeated measures of variance (ANOVA) was used to determine if a significant difference exist between hyo-laryngeal movement pattern measured at pre-NMES (baseline) compared to post-NMES (repeated measure). The effect of gender was included as a covariate to measure if a significant difference exist between male and female participants. The effect of age was included as a factor between groups, however with such a small group of participants ($n = 22$) and restricted age range (18 -25 years), no significant effects may be observed. The gender and age effect was not a main aim of this study and was additionally reported due to current literature findings that gender and age differences exist when focusing on training effect outcomes (Shaw et al., 1995; Rademaker et al., 1998; Youngsun & Gary, 2014). The detraining effect of NMES on the hyo-laryngeal movement pattern was measured by

calculating if a statistical significant difference existed between the participants that received the NMES directly prior to their second swallow exam, and the participants that received the NMES more than 60min prior to their second swallow exam. Pairwise comparisons using paired sample T-tests with significance set at $p = 0.05$ (using Bonferonni correction of 0.05 across 3 pairwise comparisons) were completed on specific dependant variables where the ANOVA reached statistical significance.

3.6. Validity and Reliability

According to Laake, Benestad and Olsen (2007) reliability is the degree of agreement between two measurement methods or situations. Reliability of all the results was ensured by making use of a single NMES device for all participants. In addition, all VFSS data was meticulously examined by the primary investigator when identifying key radiographic images from each swallowing exam for measurement purposes. Each key radiographic image selected by the primary investigator was cross-validated by an experienced SLT in VFSS who blindly evaluated the data. This blinded procedure increased inter-rater reliability of the evaluation of this study; however some would argue that in the absence of no control group the VFSS data would be of less value. The ethical implications of exposing healthy young individuals to radiation will also result in less likelihood of replication of the study.

Internal validity is defined by Thomas, Nelson and Silverman (2005) as “the extent to which the results of a study can be attributed to the treatments used in the study” (p. 13). Internal validity was ensured as the time period between pre- and post- data collection and NMES treatment were limited.

Thomas, Nelson and Silverman (2005) defined external validity with reference to generalizability of data. Findings obtained from the proposed study were based on healthy individuals with no swallowing problems, thus aiding generalizability to the wider population. However, although the degree to which these findings are absolute is not conclusive, it is likely to be statistically probable.

CHAPTER 4: RESULTS

This chapter reports on the data generated during data collection procedures and the statistical analysis thereof. The statistical significance of the data is reported according to the main aims and objectives of the study, a summary of the data is presented in tables and also visually as graphs. These findings are then discussed in chapter 5 according to the results and previous findings in the literature.

4.1. Study Participants

A total of thirty subjects were enrolled for the study and completed the initial screening swallowing assessment. Following the screening, seven subjects withdrew prior to the baseline swallow exam due to other commitments and for personal reasons as explained in chapter 3 in detail. Furthermore, one participant fainted during the NMES procedure and had to be excluded from the study until medically cleared. In total twenty-two participants completed the study and the data was analysed accordingly.

4.1.1. Participant Demographics

The aim was to enrol an equal number of male and female participants with fifteen participants from each gender. However, due to the unexpected rate of drop-outs, those remaining in the study ($n = 22$) consisted of twelve females and ten males. It is important to note that this drop-out rate did decrease statistical power of the data obtained in the study. Further recruiting of participants was not possible due to limited access to testing facilities and devices. The target age was between 18 and 25 years of age, as described in the inclusion and exclusion criteria since the study was aimed at generating normative data in young healthy participants. The average age of participants was 22 years ($SD = 1.73$), with a maximum age of 25 years and minimum age of 19 years. The breakdown according to gender is shown below in Table 14.

Table 14

Participant Age Distributions between Male and Female

Group	N	Mean (Age)	SD	SEM
Female	12	22	1.48	0.43
Male	10	22.7	2	0.63
Male & Female	22	22.32	1.73	0.37

†Values are in years and months

Adipose tissue in the neck area is shown in the literature to affect the activation of the underlying muscles, depending on the NMES electrode placement (Humbert et al., 2006). This study did not aim to report on variation of placement and the effect thereof. However neck adipose tissue of all

participants were measured for the purpose of reporting on participant demographical factors as shown below in Table 15.

Table 15

Participant Neck Adipose Tissue between Male and Female

Group	N	Mean	SD	SEM
Female	12	7.25	2.60	0.75
Male	10	4.80	1.55	0.49
Male & Female	22	6.14	2.47	0.53

†Values are in mm

NMES intensities were determined as explained in chapter 3 and recorded for each participant as shown in Appendix H. In summary female participants tolerated a higher intensity (Mean = 5.12, SD = 0.71) compared to male participants (Mean = 4.90, SD 1.07) as shown below in Table 16.

Table 16

NMES Intensities Set for Each Participant

Group	N	Mean	SD	SEM
Female	12	5.12	0.71	0.20
Male	10	4.90	1.07	0.34
Male & Female	22	5.02	0.87	0.82

†Values are in mA

4.2. Presentation of Results

4.2.1. Baseline Measurements of HLC Pre-NMES

Data were obtained from all participants (n = 22) as shown below in Table 17, full details are available in Appendix I.

Table 17

Baseline VFSS Pre-NMES (Swallowing Exam 1) Measurements

Group	Hyoid Rest Coordinates						Hyoid Elevation Coordinates						Hyoid Decent Coordinates					
	X-distance			Y-distance			X-distance			Y-distance			X-distance			Y-distance		
	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD
Female	33.57 – 49.83	41.13	4.45	9.77 – 41.07	22.89	9.36	48.43 – 64.77	55.78	5.91	16.67 – 51.37	36.20	10.54	36.6 – 52.17	42.88	4.71	13.33 – 37.10	23.64	6.74
Male	41.67 – 60.60	50.72	6	10.93 – 33.47	18.55	8.22	57.67 – 79.70	66.93	7.24	22.80 – 59.67	36.11	12.20	44 – 61.57	52.53	5.42	6.67 – 45.03	19.04	10.76
Male and Female	33.57 – 60.60	45.49	7.05	9.77 – 41.07	20.92	8.93	48.43 – 79.70	60.85	8.54	16.67 – 59.67	36.16	11.04	36.60 – 61.57	47.26	6.96	6.67 – 45.03	21.55	8.88

†Values are in mm

4.2.2. Repeated Measurements of HLC Post-NMES

Data were obtained from all participants (n = 22) as shown below in Table 18, full details are available in Appendix J.

Table 18

Follow-Up VFSS Post-NMES (Swallowing Exam 2) Measurements

	Hyoid Rest Coordinates						Hyoid Elevation Coordinates						Hyoid Decent Coordinates					
	X-distance			Y-distance			X-distance			Y-distance			X-distance			Y-distance		
Group	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD
Female	35 – 48.27	40.78	3.81	1.7 – 28.70	15.77	7.66	47.70 – 66.23	54.43	5.07	10.67 – 47.80	28.49	11.23	38.23 – 49.23	42.46	3.71	-4.67 – 27.67	14.29	8.72
Male	41.87 – 59.30	50.34	5.65	0 – 30.80	12.74	9.63	56.7 – 73.90	65.46	6.38	10.03 – 52.63	31.81	13.25	41.23 – 57.27	51.71	5.73	-5.43 – 32.90	13.01	11.56
Male and Female	35 – 59.30	45.13	6.71	0 – 30.80	14.40	8.54	47.7 – 73.90	59.44	7.91	10.67 – 52.63	30.00	12.00	38.23 – 57.27	46.66	6.60	-5.43 – 32.90	13.71	9.88

†Values are in mm

4.2.3. Effect of a 14 minute NMES session on the HLC movement pattern

ANOVA between subjects was performed using the raw data obtained from swallowing exam 1 (pre-NMES) and swallowing exam 2 (post-NMES) to test for any statistical significant effect of the stimulation. This effect was measured across all six time points (dependent variables), namely: at rest pre-NMES, maximum elevation pre-NMES, at maximum descent pre-NMES, at rest post-NMES, at maximum elevation post-NMES and at maximum descent post-NMES. The measurements included in this initial analysis consisted of all the x-distance's (anterior movement of the HLC) at each time point and as well as all the y-distance's (elevation of the HLC) for each time point in order to evaluate the effect over time. Furthermore the groups were analysed according to gender so as to determine whether gender differences displayed significant effects on anterior movement or elevation of the HLC over time (pre- and post-NMES). This is represented in Figure 18 below: genders are shown separately over the 6 time points.

4.2.3.1. Analysis of the anterior movement of the HLC across all six time points (combined pre- and post-NMES)

When one compares the data as a group with ANOVA, the anterior movement of the HLC showed that there was a highly significant statistical difference in the anterior movement of the HLC over the six time points found (Wilks Lambda = 0.043; $F(5, 16) = 70.82$, $p = 0.01$) as shown in Table 19 and Figure 18 below. Furthermore, the grouping according to gender showed no significant statistical difference over the same time points between gender groups (Wilks Lambda = 0.93, $F(5, 16) = 0.23$, $p = 0.94$). This finding illustrates the significant differences in HLC movement from rest to elevation and back to decent position over all six time points. It confirms the literature by Wijting & Freed (2003) reporting on normal HLC movement pattern, providing a visual presentation thereof in Figure 18 below.

When one analyses the data for change within subject in the groups, a statistically significant effect was seen in the anterior movement of the HLC in the combined pre- and post-NMES ($p = 0.01^*$). However, the same parameters within subject no longer showed significant differences when gender was taken into account ($p = 0.58$).

Table 19

ANOVA Analysis of Anterior Movement (X-Distances) of the HLC across All Six Time Points and Gender:

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.04	70.82 ^b	5.00	16.00	.01*
Time * Gender	Wilks' Lambda	0.94	0.23 ^b	5.00	16.00	0.94

* significance at $p < 0.05$

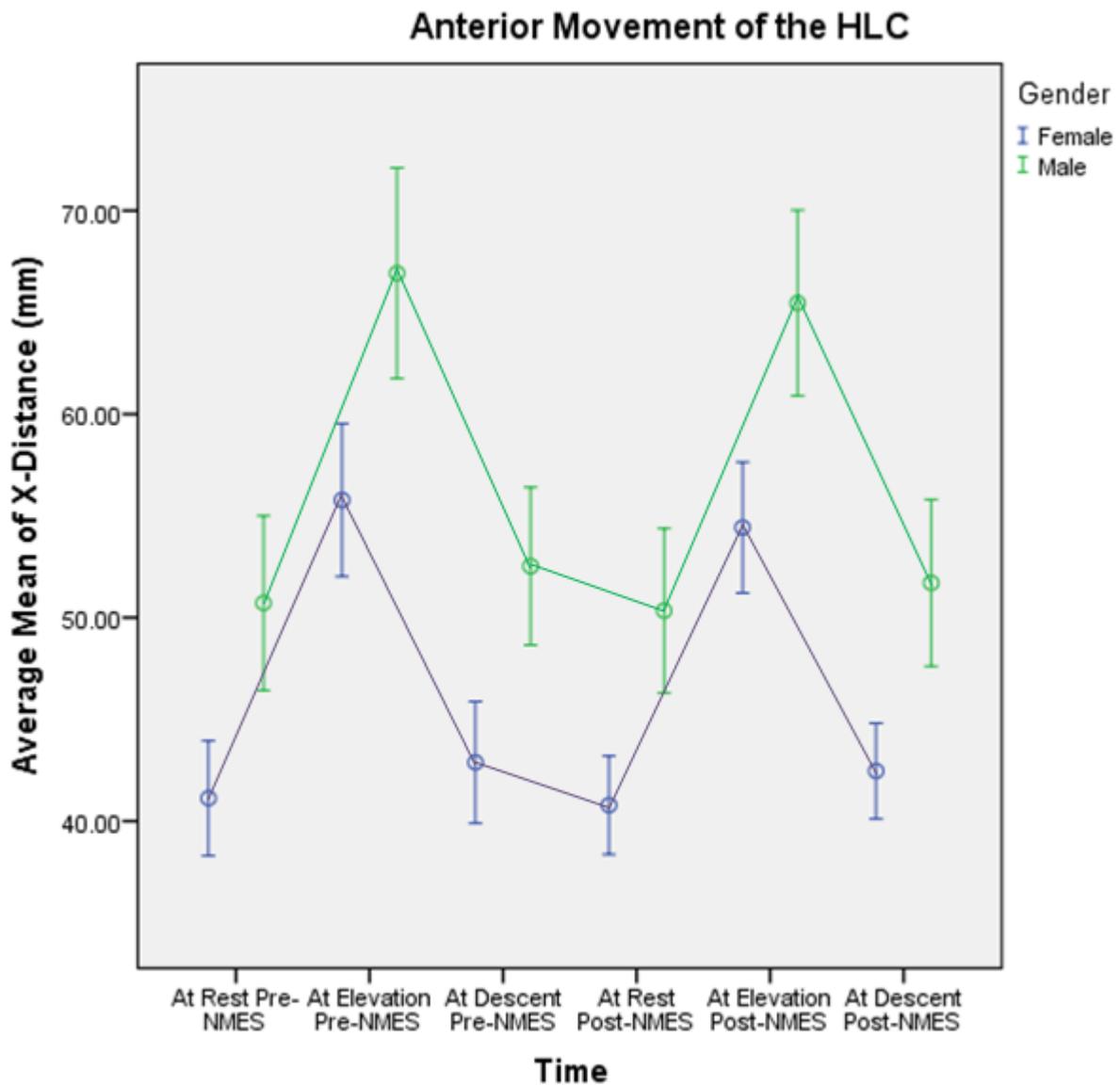


Figure 18. Anterior movement of the HLC across all six time points (combined pre- and post-NMES) and gender: Vertical bars indicate 95% confidence interval of the means

4.2.3.2. Analysis of the elevation of the HLC across all six time points (pre- and post-NMES)

The comparison of the data as a group with ANOVA (measuring the elevation of the HLC) showed that there was a highly significant difference in the elevation of the HLC over the six time points found (Wilks Lambda = 0.09, $F(5, 16) = 31.02$, $p = 0.01^*$) as shown in Table 20 and Figure 19 below. However, differences in the groups according to gender did not show any statistically significant differences (Wilks Lambda = 0.79, $F(5, 16) = 0.86$, $p = 0.53$). This finding illustrates the significant differences in HLC movement from rest to elevation and back to decent position over all six time points. It supports the literature by Wijting & Freed (2003) reporting on normal HLC movement pattern, providing a visual presentation thereof in Figure 19 below.

Similarly, when changes within subject in each group was analysed, the change in elevation of the HLC across all six time points was significant ($p = 0.01^*$). Within subjects in each group, no significant change in the elevation measurement of the HLC was measurable ($p = 0.18$) even when gender was taken into account ($p = 0.66$).

Table 20

ANOVA Analysis of Elevation (Y-Distances) of the HLC across All Six Time Points and Gender:

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	.09	31.02 ^b	5.00	16.00	0.01*
Time * Gender	Wilks' Lambda	0.79	0.86 ^b	5.00	16.00	0.53

* significance at $p < 0.05$

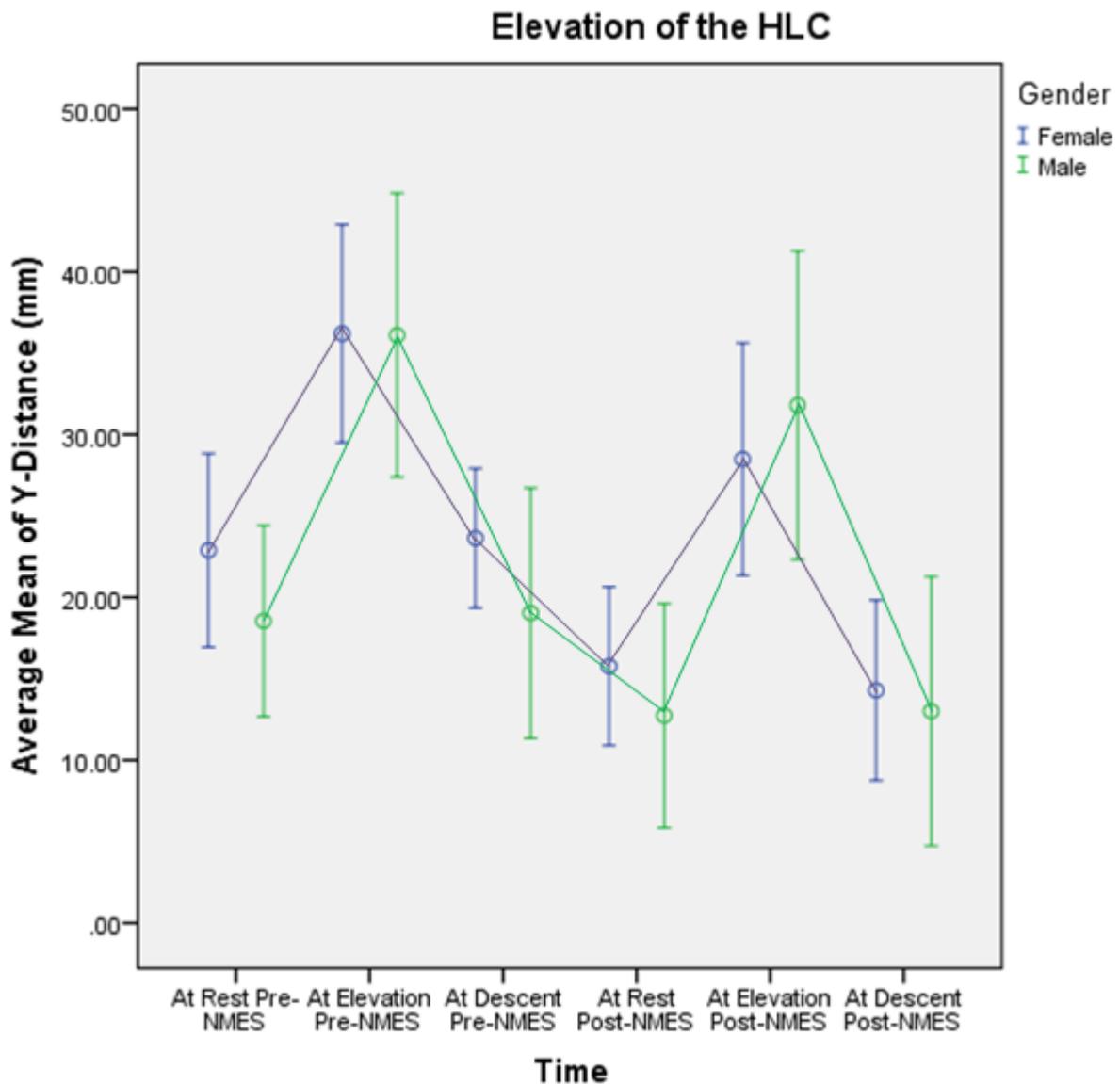


Figure 19. Elevation of the HLC across all six time points (pre- and post-NMES) and gender: Vertical bars indicate 95% confidence interval of the means

4.2.4. Post Hoc Tests to determine the effect on the HLC pre- to post-NMES over all six time points

Since ANOVA revealed significant effects on anterior movement of the HLC and elevation of the HLC across all six time points (pre- and post-NMES), post hoc tests were required to determine whether comparison of specific points of measurements also revealed significant differences. Paired samples T-test were therefore applied to compare anterior movement of the HLC pre- to post- NMES. A second paired sample T-test set was done to compare elevation of the HLC pre- to post- NMES.

Changes in anterior movement of the HLC pre-NMES (M = 51.20, SD = 7.28) to post- NMES (M = 50.41, SD = 6.85) were statistically different ($t(21) = 1.8$, $p = 0.09$). Similarly, the second paired samples T-test applied to the y-distances pre-NMES to post-NMES indicated a significant difference: pre-NMES (M = 26.21, SD = 8.94) to post-NMES (M = 19.37, SD = 9.58). ($t(21) = 4.66$, $p = 0.01^*$) as shown in Table 21 and 22 below.

Table 21

Paired Samples Statistics to Compare Differences in Anterior Movement of the HLC and Elevation of the HLC Over All Six Time Points Pre- to Post-NMES

		Mean	N	SD	SEM
Pair 1	Average X-distance pre-NMES	51.20	22	7.28	1.55
	Average X-distance post-NMES	50.41	22	6.85	1.46
Pair 2	Average Y-distance pre-NMES	26.21	22	8.94	1.91
	Average Y-distance post-NMES	19.37	22	9.58	2.04

†Values are in mm

Table 22

Paired Samples T-test to Compare Differences in Anterior Movement of the HLC and Elevation of the HLC over All Six Time Points Pre- to Post-NMES

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	SD	SEM	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Average X-distance pre-NMES and post-NMES	0.79	2.06	0.44	-0.12	1.70	1.80	21	0.09
Pair 2	Average Y-distance pre-NMES and post-NMES	6.84	6.90	1.47	3.79	9.90	4.66	21	0.01*

* *significance at $p < 0.05$*

4.2.5. Analysis of the anterior movement of the HLC pre-NMES versus post-NMES:

Since the analysis of the anterior movement across all six time points by ANOVA showed significant differences, it was decided to compare the same measurements at individual time points by comparing the average at rest, at maximum elevation and at descent (pre-NMES) to the same measurements (at rest, at elevation and at descent) post-NMES. The aim was to determine whether the NMES had any impact on the HLC positioning at any specific position. ANOVA showed that there was no significant difference in the anterior movement of the HLC pre- and post-NMES (Wilks Lambda = 0.87, $F(1, 20) = 3.13$, $p = 0.09$) as shown in Table 23 and Figure 20 below. Inclusion of gender as a covariate factor into the ANOVA showed no significant effect on the measurements (Wilks Lambda = 1, $F(1, 20) = 0.04$, $p = 0.8$ (Table 23, Figure 20 below).

Analysis of within subject effects did not change the level of statistical significance (pre- versus post-NMES; $p = 0.09$). Similarly, gender as a covariate did not change the calculated level of significance pre- versus post-NMES ($p = 0.084$). This is also represented graphically in Figure 20 below.

Table 23

ANOVA of Average Anterior Movement of the HLC Pre- Versus Post-NMES and Gender:

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.87	3.13 ^b	1.00	20.00	0.09
Time * Gender	Wilks' Lambda	1.00	0.04 ^b	1.00	20.00	0.08

* significance at $p < 0.05$

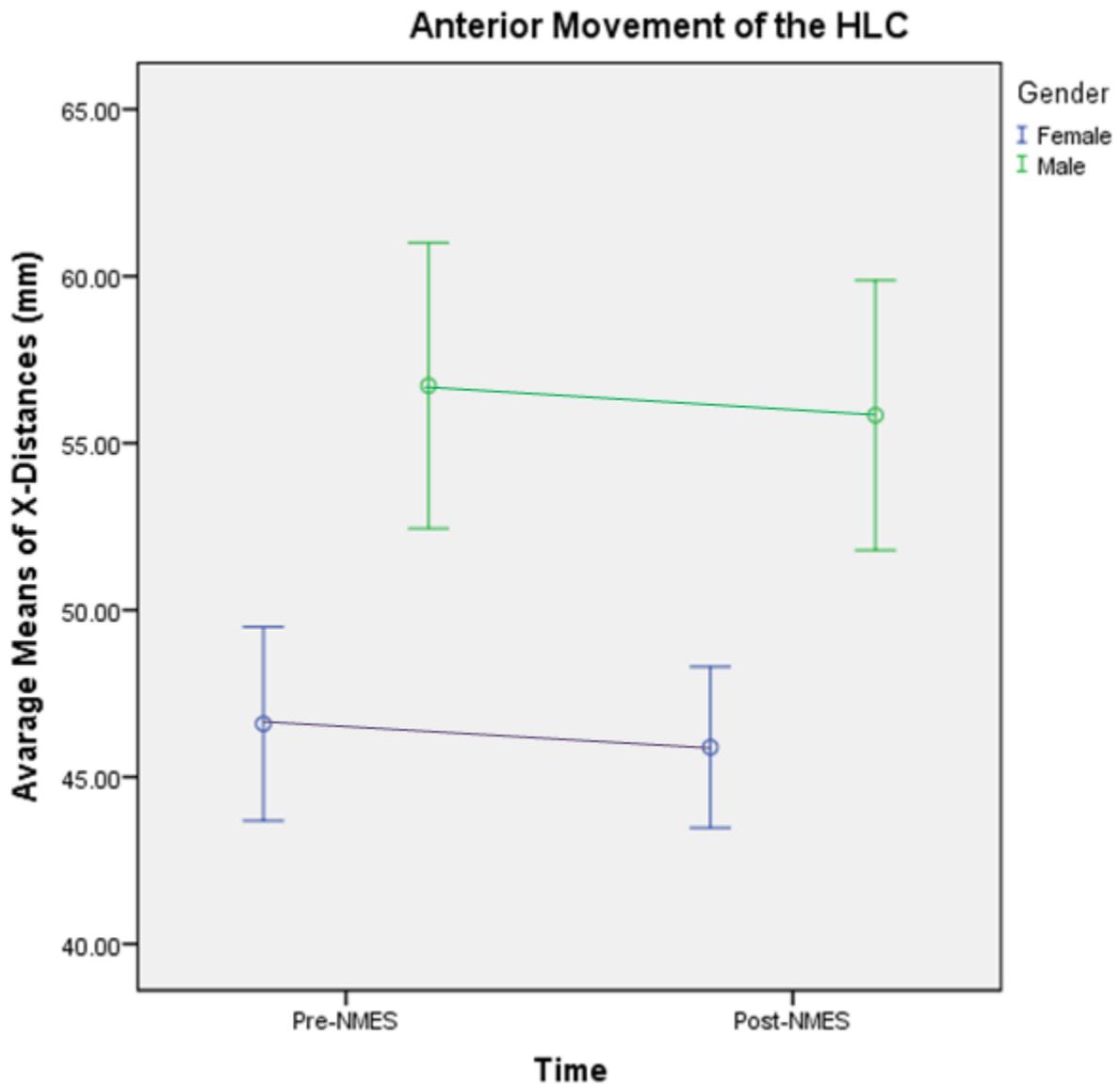


Figure 20. Anterior movement of the HLC pre-NMES versus post-NMES: Vertical bars indicate 95% confidence interval of the means

4.2.6. Analysis of elevation of the HLC pre-NMES versus post-NMES:

The data presented above indicated that there was no significant difference in the average anterior movement measurements of the HLC at pre- to post-NMES. The same comparison was therefore conducted for the average elevation measurements of the HLC pre- versus post NMES. ANOVA showed that there was a statistically significant effect between elevation of the HLC pre- and post-NMES measurements (Wilks Lambda = 0.49, $F(1, 20) = 20.55$, $p = 0.01^*$). The data is provided in Table 24 and Figure 21 below.

However, the inclusion of gender as a covariate into the ANOVA showed no significant effects in the elevation of the HLC pre- and post-NMES (Wilks Lambda = 0.96, $F(1, 20) = 0.82$, $p = 0.38$). Analysis of the measurement within subject showed a significant effect in elevation of the HLC ($p = 0.01^*$) but no gender effects ($p = 0.38$). Test of between subjects effect of gender showed no significant effect, ($p = 0.66$).

Table 24

ANOVA of Average Elevation of the HLC Over Pre- Versus Post-NME and Gender:

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.49	20.55 ^b	1.00	20.00	0.01*
Time * Gender	Wilks' Lambda	0.96	0.82 ^b	1.00	20.00	0.38

* *significance at $p < 0.05$*

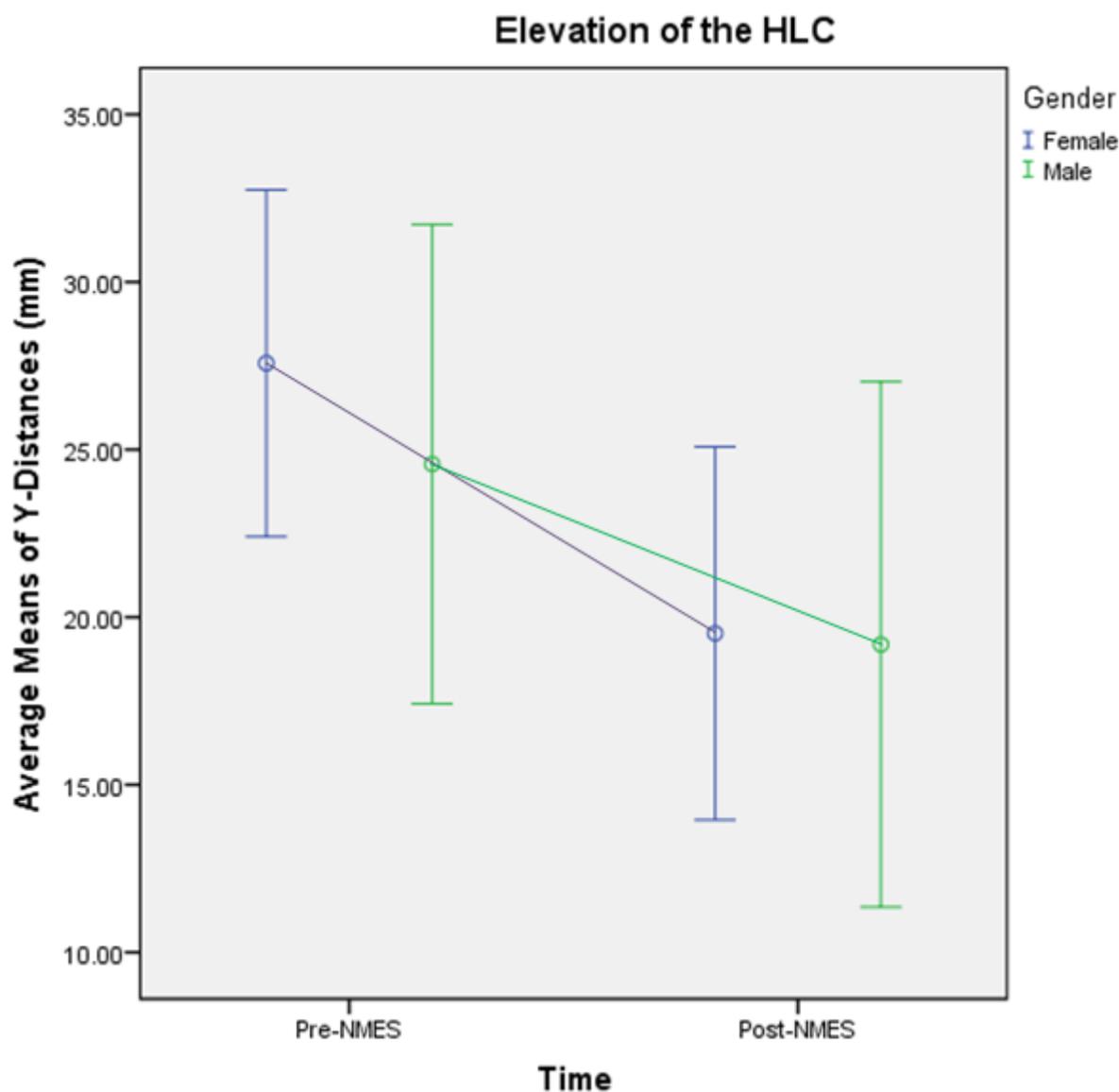


Figure 21. Elevation of the HLC pre-NMES versus post-NMES: Vertical bars indicate 95% confidence interval of the means

4.2.7. Comparison of HLC movement pattern at each position pre- and post-NMES

Further analyses of the data comparing each position of HLC (at rest, at elevation and descent) pre- and post-NMES were calculated independently.

4.2.7.1. Anterior movement of the HLC pre-NMES to post-NMES at position of hyoid rest.

Paired samples T-test was conducted to compare the anterior movement of the HLC pre- to post-NMES at position of hyoid rest. There was no significant difference in the position of the HLC at rest found: pre-NMES (M = 45.49, SD = 7.05) versus post-NMES (M = 45.13, SD = 6.71) ($p = 0.278$; Table 25 and 26).

4.2.7.2. Anterior movement of the HLC pre-NMES to post-NMES at position of hyoid elevation.

Comparison of the anterior movement of the HLC pre-versus post-NMES at position of hyoid elevation displayed no significant differences in this measurement: pre-NMES ($M = 60.85$, $SD = 8.55$) compared to post-NMES ($M = 59.44$, $SD = 7.91$) ($p = 0.85$), as shown in Table 25 and 26.

4.2.7.3. Anterior movement of the HLC pre-NMES to post-NMES at position of hyoid descent.

The third comparison was between the pre- versus post-NMES measurement of hyoid descent positioning: once again, no statistically significant effect was found between anterior movement of the HLC pre-NMES ($M = 47.27$, $SD = 6.96$) and post-NMES ($M = 46.66$, $SD = 6.59$) at descent conditions ($p = 0.19$), as shown in Table 25 and 26.

4.2.7.4. Elevation of the HLC pre-NMES to post-NMES at position of hyoid rest.

Similarly paired samples T-test were conducted comparing elevation of the HLC pre-NMES to post-NMES at position of hyoid rest. There was a significant effect found between elevation of the HLC pre-NMES ($M = 20.92$, $SD = 8.93$) and elevation of the HLC post-NMES ($M = 14.39$, $SD = 1.82$) at rest conditions; $t(21) = 4.12$, $p = 0.01^*$, as shown in Table 25 and 26.

4.2.7.5. Elevation of the HLC pre-NMES to post-NMES at position of hyoid elevation.

The comparison of the measurements in the elevation of the HLC pre-and post-NMES showed a significant effect between elevation of the HLC pre-NMES ($M = 36.16$, $SD = 11.04$) and elevation of the HLC post-NMES ($M = 30$, $SD = 12$) at elevation conditions; $t(21) = 3.76$, $p = 0.01^*$, as shown in Table 25 and 26.

4.2.7.6. Elevation of the HLC pre-NMES to post-NMES at position of hyoid elevation

A sixth paired samples T-test were conducted comparing descent of the HLC pre-NMES to post-NMES at position of hyoid descent. There was a significant effect found between descent of the HLC pre-NMES ($M = 21.55$, $SD = 8.88$) and descent of the HLC post-NMES ($M = 13.71$, $SD = 9.88$) at descent conditions; $t(21) = 4.99$, $p = 0.01^*$, as shown in Table 25 and 26.

Table 25

Paired Samples Statistics to Compare Differences in Anterior Movement and Elevation of the HLC at Hyoid Position (Rest, Elevation and Descent) Pre- and Post-NMES

		Mean	N	SD	SEM
Pair 1	X-distance at rest pre-NMES	45.49	22	7.05	1.50
	X-distance at rest post-NMES	45.13	22	6.71	1.43
Pair 2	X-distance at elevation pre-NMES	60.85	22	8.55	1.82
	X-distance at elevation post-NMES	59.44	22	7.91	1.69
Pair 3	X-distance at descent pre-NMES	47.27	22	6.96	1.48
	X-distance at descent post-NMES	46.66	22	6.59	1.41
Pair 4	Y-distance at rest pre-NMES	20.92	22	8.93	1.90
	Y-distance at rest post-NMES	14.39	22	8.54	1.82
Pair 5	Y-distance at elevation pre-NMES	36.16	22	11.04	2.35
	Y-distance at elevation post-NMES	30.00	22	12.00	2.56
Pair 6	Y-distance at descent pre-NMES	21.55	22	8.88	1.89
	Y-distance at descent post-NMES	13.71	22	9.88	2.11

†Values are in mm

Table 26

Paired Samples T-test to Compare Differences in Anterior Movement and Elevation of the HLC at Hyoid Position (Rest, Elevation and Descent) Pre- and Post-NMES

Paired Samples Test									
		Paired Differences					t	df	Sig. (2-tailed)
		Mean	SD	SEM	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	X-distance at rest pre-NMES – X-distance at rest post-NMES	0.36	1.52	0.32	-0.31	1.03	1.11	21	0.28
Pair 2	X-distance at elevation pre-NMES – X-distance at elevation post-NMES	1.40	3.65	0.78	-0.21	3.02	1.81	21	0.09
Pair 3	X-distance at descent pre-NMES – X-distance at descent post-NMES	0.60	2.06	0.44	-0.31	1.52	1.37	21	0.19
Pair 4	Y-distance at rest pre-NMES – Y-distance at rest post-NMES	6.53	7.43	1.58	3.23	9.82	4.12	21	0.01*
Pair 5	Y-distance at elevation pre-NMES – Y-distance at elevation post-NMES	6.16	7.69	1.64	2.75	9.57	3.76	21	0.01*
Pair 6	Y-distance at descent pre-NMES – Y-distance at descent post-NMES	7.84	7.37	1.57	4.57	11.11	4.99	21	0.01*

* significance at $p < 0.05$

4.3. Reversibility/Detraining Effects of NMES on HLC

Out of all the participants in this study only four participants underwent VFSS within 60 minutes of completing their second swallowing exam (post-NMES). These four participants were identified as the non-detrained group and the rest of the participants identified as the detraining group. The aim was to compare the detraining group to the non-detraining group to observe the reversibility effect as described in the literature by Powers and Howley, (2007). This could imply a detraining effect of the NMES: the longer the waiting period between stimulation and VFSS, the longer the period of detraining.

4.3.1. Comparison of the anterior movement measurements of the HLC across all six time points (combined pre- and post-NMES): detrained versus non-detrained group

ANOVA analysis of the data including all the x-distance's (anterior movement of the HLC) for the detraining group (n=18) versus the non-detraining group (n = 4) revealed that there was a highly significant difference on anterior movement of the HLC (x-distances) over the six time points (Wilks Lambda = 0.08, $F(5, 16) = 31.47$, $p = 0.01$). This is shown in Table 27 and Figure 22).

Table 27

ANOVA of Anterior Movement of the HLC over Time and Time by Detraining (Pre- Versus Post-NMES)

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.08	39.47 ^b	5.00	16.00	.001*
Time * Detraining	Wilks' Lambda	0.83	0.68 ^b	5.00	16.00	0.65

* significance at $p < 0.05$

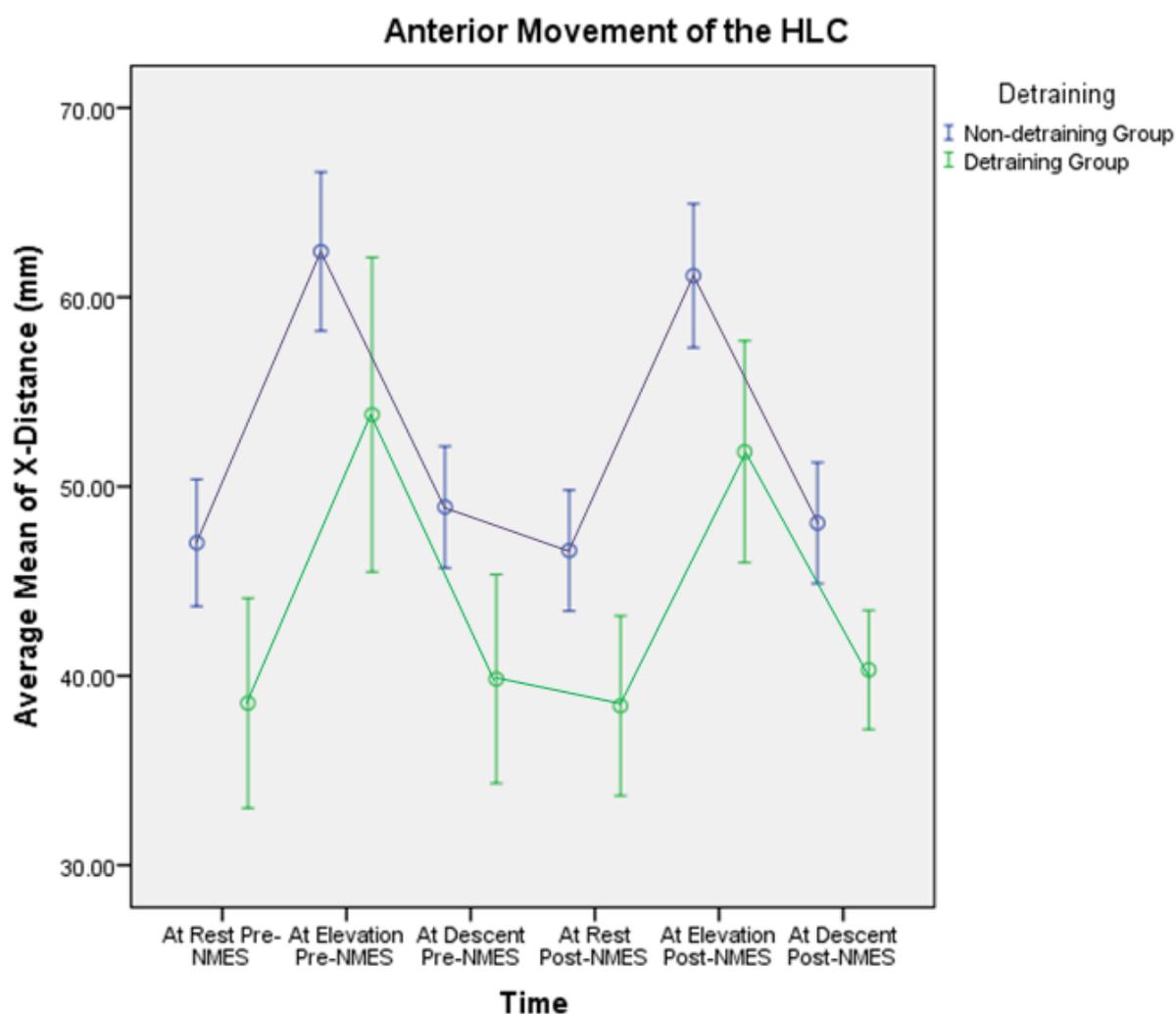


Figure 22. Anterior movement of the HLC across all six time points (combined pre- and post-NMES): detrained versus non-detrained group: Vertical bars indicate 95% confidence interval of the means

4.3.2. Comparison of the elevation measurements (y-distances) of the HLC across all six time points (combined pre- and post-NMES): detrained versus non-detrained group

When one compares the same data for the y-distance's (elevation of the HLC) for the detraining group (n=18) and the non-detraining group (n = 4) again showed a highly significant difference over the six time points (Wilks Lambda = 0.16, $F(5, 16) = 16.36$, $p = 0.01^*$), as shown in Table 28, Figure 23.

Table 28

ANOVA of Elevation of the HLC over Time and Time by Detraining (Pre- Versus Post-NMES)

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.16	16.36 ^b	5.00	16.00	.001*
Time * Detraining	Wilks' Lambda	0.77	0.98	5.00	16.00	0.46

* significance at $p < 0.05$

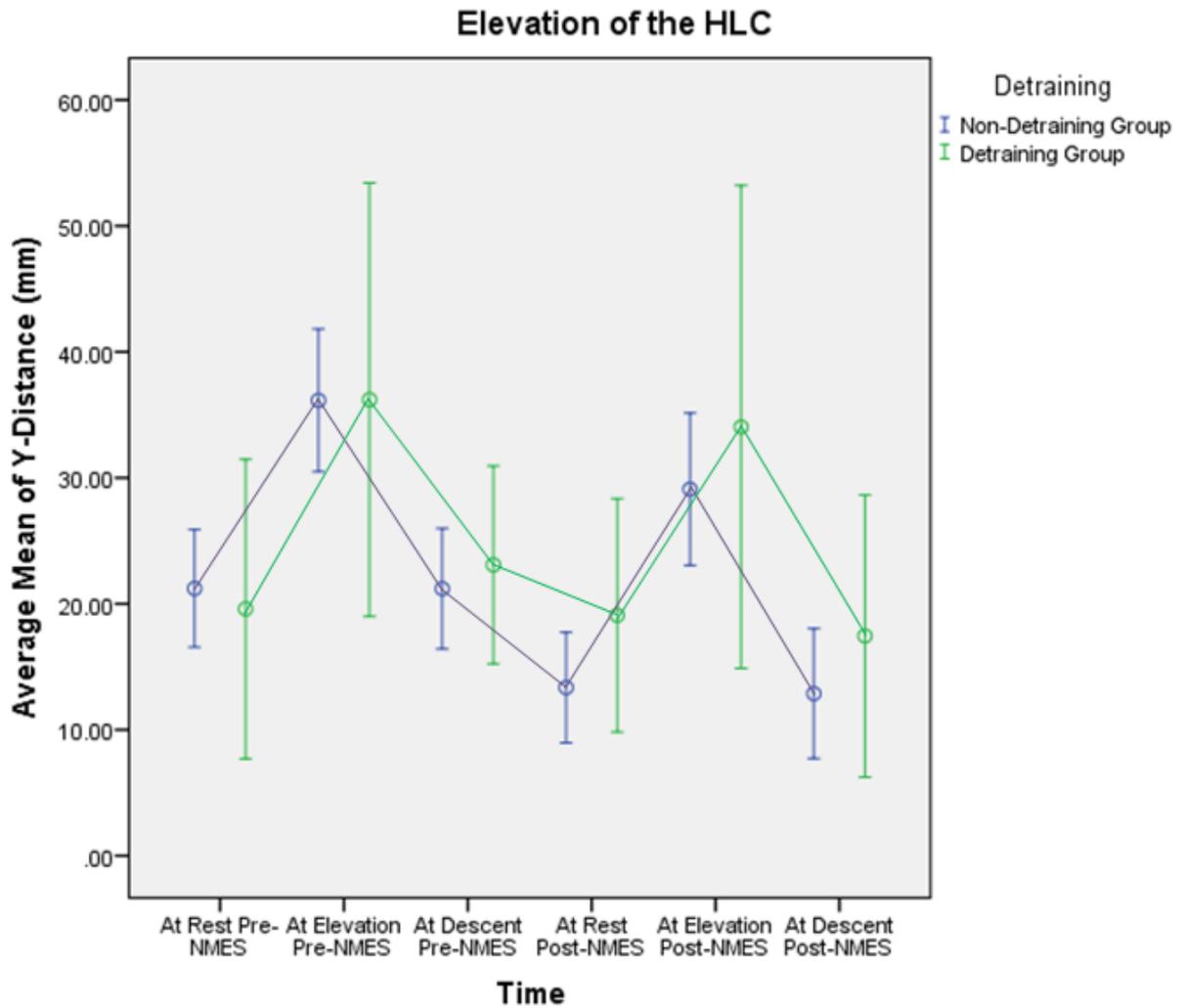


Figure 23. Elevation of the HLC across all six time points (combined pre- and post-NMES): detrained versus non-detrained group: Vertical bars indicate 95% confidence interval of the means

4.3.3. Anterior movement of the HLC pre-NMES versus post-NMES): detrained versus non-detrained group

ANOVA analysis of the data including all the x-distance's (anterior movement of the HLC) for the detraining group (n=18) and the non-detraining group (n = 4) across all six time points of the study an average of pre-NMES (at rest pre-NMES, at elevation pre-NMES, at descent pre-NMES) compared to average of post-NMES (at rest post-NMES, at elevation post-NMES and at descent post-NMES) were done.

ANOVA showed that there was no significant effect between anterior movement for the detrained group (n=18) and the non-detrained group (n = 4), HLC pre- and post-NMES measurements, (Wilks Lambda = 0.07, $F(1, 20) = 1.42$, $p = 0.25$) as shown in Table 29 and Figure 24. Including detraining as a covariate factor into the ANOVA showed no significant effect between anterior movement of the HLC pre- and post-NMES; (Wilks Lambda = 0.98, $F(1, 20) = 0.70$, $p = 0.8$), as shown in Table 29 and Figure 24. Test of within subject contrast showed no significant difference in anterior movement of the HLC pre- and post-NMES between detraining; $p = 0.78$. Test of between subjects effect of detraining showed a significant effect, $p = 0.02$.

Table 29

ANOVA of Anterior Movement of the HLC over Time and Time by Detraining (Pre- Versus Post-NMES)

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.07	1.42 ^b	1.00	20.00	0.25
Time * Detraining	Wilks' Lambda	0.77	0.70	1.00	20.00	0.80

* significance at $p < 0.05$

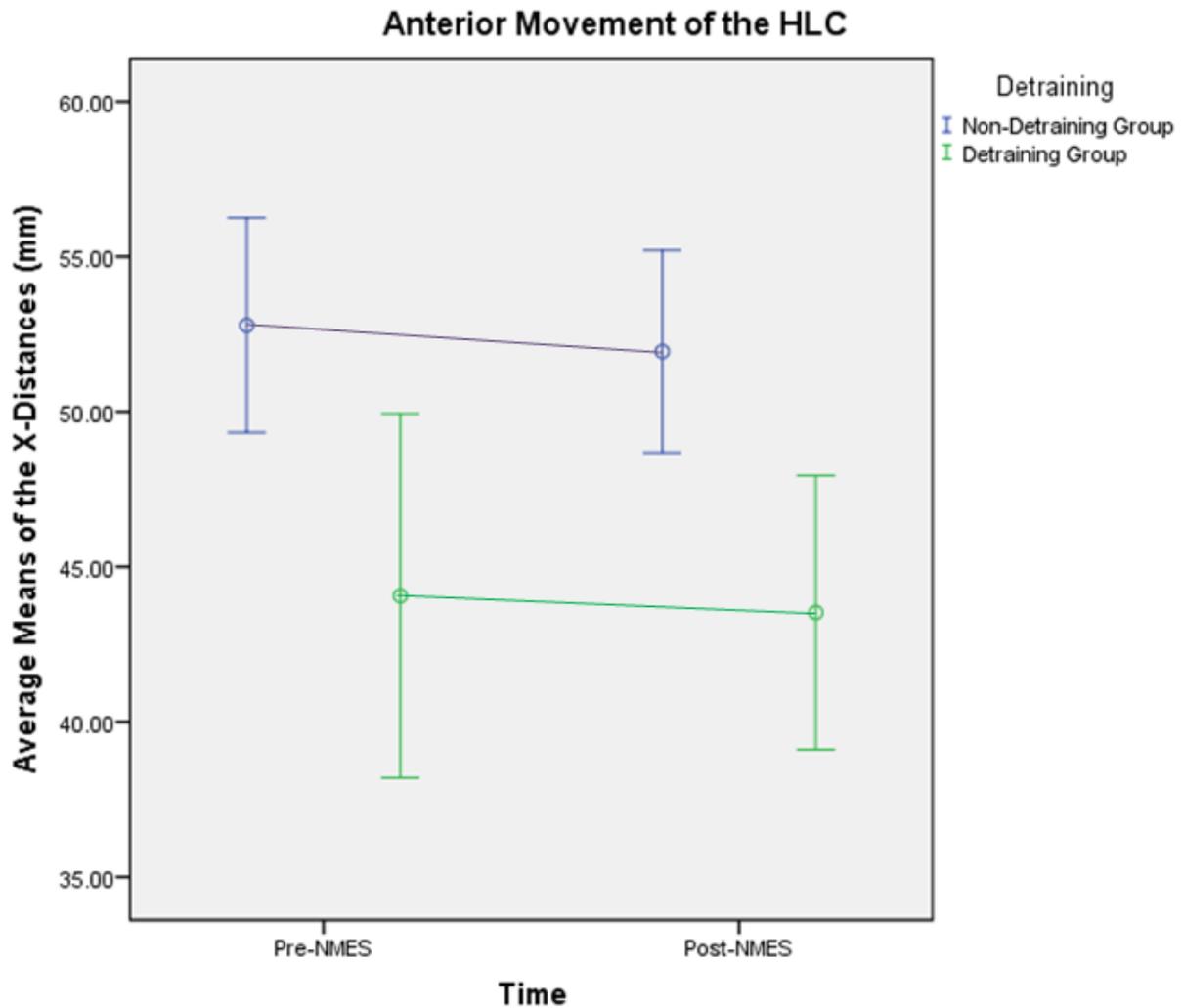


Figure 24. Anterior movement of the HLC pre-NMES versus post-NMES: Vertical bars indicate 95% confidence interval of the means

4.3.4. Elevation of the HLC (pre-NMES versus post-NMES): detrained versus non-detrained group

ANOVA analysis of the data including all the y-distances (elevation of the HLC) for the detraining group (n=18) and the non-detraining group (n = 4) across all six time points of the study an average of pre-NMES (at rest pre-NMES, at elevation pre-NMES, at descent pre-NMES) compared to average of post-NMES (at rest post-NMES, at elevation post-NMES and at descent post-NMES) were done.

ANOVA showed that there was a significant effect between elevation for the detraining group (n=18) and the non-detraining group (n = 4), HLC pre- and post-NMES measurements; (Wilks Lambda = 0.72, $F(1, 20) = 7.90$, $p = 0.01^*$) as shown in Table 30 and Figure 25. Including detraining as a covariate factor into the ANOVA showed no significant effect between elevation of the HLC pre- and post-NMES; (Wilks Lambda = 0.92, $F(1, 20) = 1.77$, $p = 0.20$) as shown in Table 30, and Figure 25.

Test of within subject contrast showed a significant difference in elevation of the HLC pre- and post-NMES between detraining; ($p = 0.01^*$). Test of between subjects effect of detraining showed no significant effect, ($p = 0.60$).

Table 30

ANOVA of Elevation of the HLC over Time and Time by Detraining (Pre- Versus Post-NMES)

Effect		Value	F	Hypothesis df	Error df	Sig.
Time	Wilks' Lambda	0.72	7.90 ^b	1.00	20.00	0.01*
Time * Detraining	Wilks' Lambda	0.92	1.77	1.00	20.00	0.20

* significance at $p < 0.05$

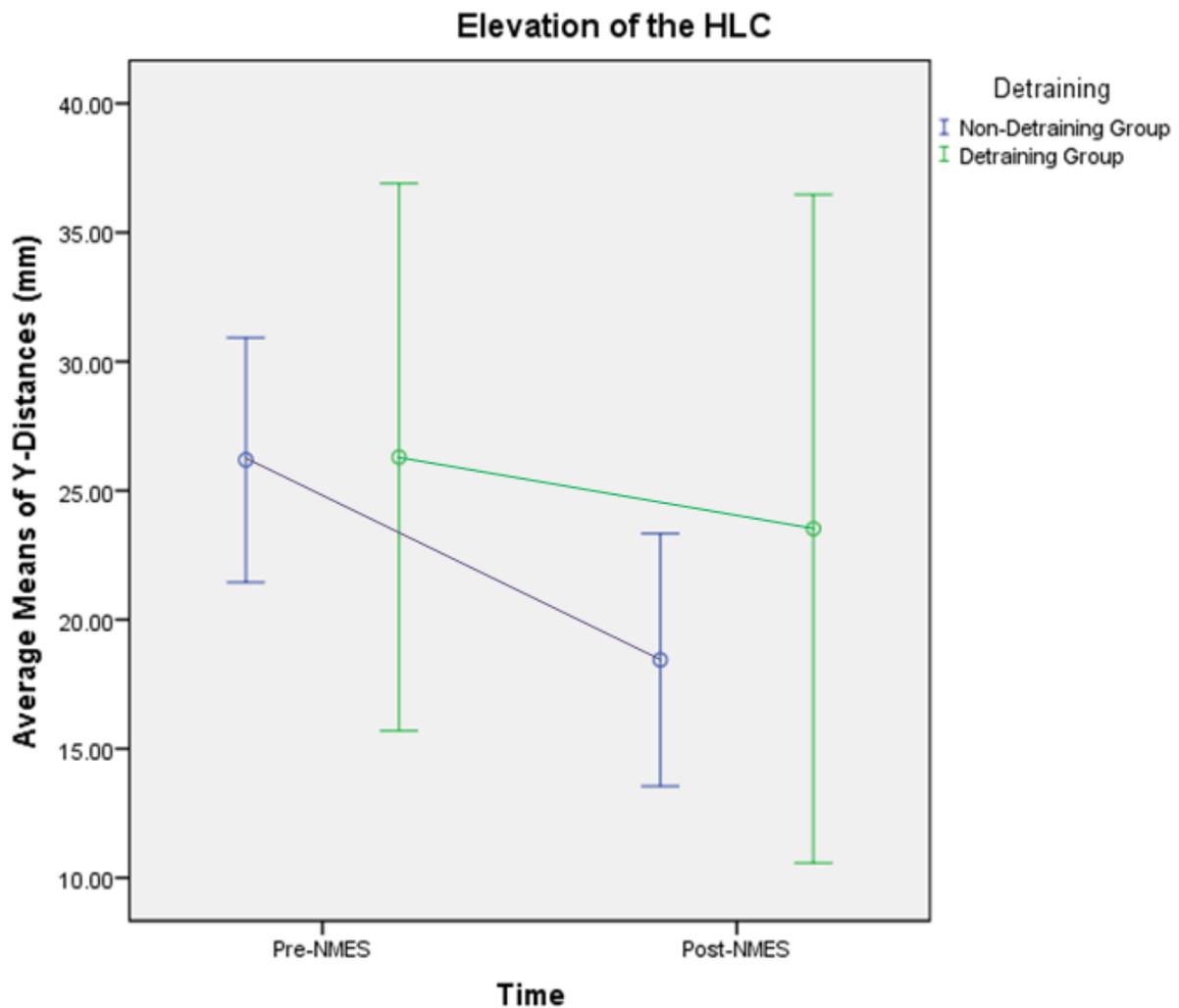


Figure 25. Elevation of the HLC pre-NMES versus post-NMES: Vertical bars indicate 95% confidence interval of the means

CHAPTER 5: DISCUSSIONS

In this chapter the results reported in chapter 4 will be interpreted and discussed. The interpretations and discussions will be presented according to each objective and will be discussed in the light of current literature for the purpose of understanding and determining to what extent NMES influenced the movement pattern of the HLC in healthy young individuals. Limitations of the study will be discussed and recommendations for future directions will be identified.

Below follows a summary of the main findings of the study:

- It was found that the HLC changes from rest position to elevation and return to descent position during normal swallowing movement pattern were statistically significantly.
- It was found that gender differences did not play a significant role in the change of these positions of the HLC movement pattern post NMES stimulation. However, baseline measurements prior to stimulation clearly indicated that gender differences existed in the elevation of the HLC.
- We showed that the anterior movement pattern does not change significantly with a single 14 minute NMES session.
- It was found that elevation of the HLC decreased significantly with a single 14 minute NMES session.
- Interestingly, the detraining effect (post-NMES) is reversible and takes place shortly after a single session of NMES.

5.1. Baseline measurements regarding HLC movement in young healthy individuals prior to NMES.

The movement pattern of the HLC serves to protect the airway in healthy individuals in that, during swallowing, the HLC movement occurs in an anterior and superior movement pattern. Swallowing disorders are most prevalent amongst the elderly (aged >50 years), patients with stroke as well as head and neck cancer patients (Logeman et al., 1997; Shaker et al., 2002; Ludlow et al., 2007). To date, the effects of NMES using the VitalStim® apparatus has been determined using patients with known swallowing disorders and very few have been conducted in healthy subjects. This study however focused on young healthy individuals in order to contribute to the sparse literature currently available (Kendall et al., 2000; Suiter et al., 2006; Doeltgen et al., 2008; Park et al., 2009; Oh et al., 2011; Heck et al., 2012). Our study is unique in many aspects: first, no normative data is available in order to compare data generated in patient populations and secondly, no studies have reported on exact measurements of the HLC in relation to NMES at specific reference points of measurements as described in the Materials and Methods section.

All participants in this study presented with this HLC movement pattern at baseline. However, differences exist between genders: this is possibly due to differences in length of anatomical structures, musculature, size and muscular strength. These findings are in agreement with research done by Molfenter & Steele, (2014). The sample size in this study was a good representation of healthy male and female individuals between the ages of 18 – 25 years (Mean Age = 22.32, SD = 1.73) and yielded higher statistical power than a similar study conducted by Humbert et al. (2006). In their study, these authors only included 6 participants between the ages of 20 -39 years (Mean = 29.8, SD = 4.5). The participants in this study had similar laryngeal adipose tissue (Mean = 6.14, SD = 2.47) compared to current literature by Humbert et al. (2006), (Mean = 5.8). The present study followed the strict protocol of the Vitalstim® Therapy System for selecting stimulation intensities for males (Mean = 4.90, SD = 1.07) and females (Mean = 5.12, SD = 0.71) whereas Humbert et al. (2006) applied maximal intensity with much higher intensities for males (Mean = 9.1, SD = 4.5) and females (Mean = 6.4, SD = 1.9). The difference in stimulation intensities used between our study and that of Humber et al. (2006) deserves further discussion.

A significant change was observed between the degree of anterior movement of the HLC between each position (rest, elevation and descent) for both male and female participants at the baseline swallowing exam. More importantly there was a significant difference in anterior movement of the HLC between genders. Male participants showed greater anterior movement of the HLC than females at baseline. These findings are in contrast to those of Humbert et al. (2006): these authors reported that NMES did not produce significant anterior movement of the HLC. We propose that due to differences in the intensities and duration of the stimulation used could account for the measured differences: Humbert et al. (2006) used maximal electrical intensity in all subjects (N = 6), significantly higher than those recommended by VitalStim® Therapy System as well as those applied in the current study. Furthermore, possible explanations for differences observed in the anterior movement of the HLC measured in our study and that of Humbert et al. (2006) could be due to the placement of the electrode of the apparatus: these investigators used 10 different electrode placement configurations to the anterior neck to determine the differences between electrode placements when applying NMES whereas this study made use of a single placement (VitalStim® Therapy System placement 3b) in all subjects.

Our data indicated that a significant change was observed between the degree of elevation movement of the HLC between each position (rest, elevation and descent) for male and female participants at baseline swallowing exam. Although a significant difference in anterior movement of the HLC between genders were observed, no significant difference between genders for elevation of the HLC at baseline was observed. Female HLC movement pattern started at a lower position than males, moved to the same position at elevation than males and returned to a lower position at descent than that of male participants. To our knowledge, these gender differences have not been reported to date

and future studies should take these findings into account when applying the technology for the clinical management of patients.

5.2. The effect of NMES on the movement patterns of the HLC after a 14 minute NMES session.

In order to determine the effect of NMES on the movement pattern of the HLC over time, the data was statistically analysed as a whole data set over the full duration of the study (including all six time points). In a secondary analysis, the effect of the NMES on the movement pattern of the HLC pre-NMES versus post-NMES was analysed at each point of reference, namely at rest, at elevation and at descent and statistical significance was determined.

The data showed a significant change in the movement pattern of the HLC in both anterior movement as well as elevation across all six time points. The degree of change measured in our study was consistent with previous literature: Perlman et al., (1995) as well as Zu et al., (2011) reported that videofluoroscopic imaging of the swallow in healthy individuals demonstrated significant changes in the positioning of the HLC from baseline to anterior placement followed by elevation. These authors however did not use any stimulation during these imaging studies. When we analysed our data post-stimulation and included gender as a covariate factor (while assessing anterior movement of the HLC), no significant change in the movement pattern of the HLC could be found. This points to the fact that when the stimulation protocol is applied, no gender differences between HLC movement pattern is present in comparison to the same measurement prior to the stimulation. These findings imply that males and females share similar swallowing kinematics upon stimulation although at baseline the genders do demonstrate differences in their HLC at rest.

Within subject effects showed significant change over time for anterior movement and elevation of the HLC, but no significant effect for time by gender. However the analysis of within subject effects for elevation of the HLC showed a trend towards significance as opposed to less significant change to the anterior movement changes of the HLC. These findings might be due different NMES intensities used: in our study, the intensity of stimulation was self-determined by each subject. They reported a “comfortable” level setting hence leading to the varied intensities reported earlier. It could be that some intensities used had no physiological impact on the HLC movement and that such data set may contribute to the overall negating of the positive effects of the NMES. This factor has been highlighted as one of the major limitations of the current study.

When comparing the average anterior movement of the HLC pre-NMES to the same measurement post-NMES, we could not demonstrate any significant effects of the stimulation on the anterior

movement of the HLC. However, when similar comparison was applied to the elevation of the HLC, a significant difference was observed between pre- and post-NMES. This finding implies that NMES may affect predominantly the elevation of the HLC rather than its anterior movement: this means that the omohyoid and sternohyoid muscles, responsible for descent of the HLC, are more affected than the thyrohyoid muscles, responsible for the elevation of the HLC. The reason for this phenomenon is argued in the literature by Humbert et al. (2006) that the thyrohyoid muscles are situated superficially in the anterior neck area and overlies the deeper omohyoid and sternohyoid muscles. In order to achieve the stimulation of the omohyoid and sternohyoid muscles, it may require longer stimulation and more frequent stimulation protocols so that long term benefit (elevation of the HLC) is measurable. This was the rationale for the development of newer technologies as reported by Michou et al. (2012) and Jayasekeran et al. (2010) whereby the stimulation electrodes are introduced directly to the pharyngeal layer (via a nasal catheter) in order to attain the deeper lying muscles. This is the basis of the Phagenyx® technology which operated differently to the instrument used in our study.

Another possibility could be the onset of muscular fatigue during NMES or that post-NMES may decrease the functional capacity of the HLC. However with adequate recovery post-NMES over a longer period of time (in order for muscle adaptations to take place), this might result in the opposite outcome (Powers & Howley, 2007). In research published by Oh et al. (2011); NMES was applied 60 minutes per day, five days per week for two weeks. They found significant improvements on the HLC post-NMES. Similarly research by Park et al. (2009) indicated that NMES applied for 20 minutes, ten times per week for two weeks resulted in an improved hyoid excursion post-NMES. However according to Powers and Howley (2007) muscle strength adaptation requires at least twelve weeks of therapy in order for the impact to be significant.

5.3. The detraining effects post NMES on the movement patterns of the HLC.

Our finding that detraining/reversibility of the stimulation could impact on the measured outcomes was very interesting. Although the groupings were different (n = 4 in the non-detrained group versus n = 18 in the detrained group) it appears that the elevation of the HLC was impacted the longer the wait between the stimulation and the VFSS imaging procedure. The time elapsed between the stimulation and imaging was significantly different between these groups: the non-detrained group underwent the stimulation protocol with immediate imaging (average time lapse of 33 minutes) whereas in the detrained group the corresponding time lapsed was 306 minutes.

Although no significant effect on anterior movement of the HLC could be found between the detrained versus non-detrained group (pre-versus post-NMES), there was a significant difference

when comparing the elevation of the HLC post NMES: the detrained group showed significantly higher elevation of the HLC in comparison to the non-detrained group. The measurements indicate that the detrained group had recovered close to their baseline elevation of the HLC within a period of six hours whereas the non-detrained group were still significantly lower relative to their baseline measurements. This shows that not only does NMES lower HLC elevation, but the reversibility thereof was observed in our study.

If one takes into consideration normal muscle physiology and the effects of training on muscle fiber distribution and glycolytic enzyme activity (as reported by Mujika & Padilla, 2001) one could speculate and extrapolate to the findings of the current study: a 14 minute stimulation protocol applied to the muscles involved in swallowing muscles display the desired effects. When one measured this in the non-detrained group with a time delay of 0 – 90 minutes (Mean = 21.5, SD = 41.9), whereas the detrained group had recovered and returned to their baseline placement of the HLC after a time delay of between 160 – 480 minutes (Mean = 320, SD = 116.3). Whether a single session of the stimulation would have any long term benefit if used in patients with swallowing disorders remains unknown at present but we would like to propose that repetitive sessions would ultimately lead to the desired effects of permanent elevation of the HLC in order to improve swallowing. This is supported by the study of Park et al. (2009) who showed that sustained elevation of the HLC was significant only if repetitive sessions (20 minutes per session for 3 days a week over 4 weeks) was used. This study was conducted in healthy controls.

We are not aware of any published studies to date that considered the effect of time (time lapse between stimulation and measurements) when the positions of the HLC were reported post-stimulation. Although our groupings were small, the findings are relevant and it is tempting to speculate that this should be taken into account when analysing data and it could be a contributing factor explaining differences reported in the literature.

5.4. Limitations

One needs to consider that due to unexpected drop-out rate the intended number of participants was not achieved. The aim was to enrol an equal number of male and female participants with fifteen participants from each gender. After the drop-outs occurred the study was completed with 12 females and 10 males, this may have contributed to Type II error and might not yield as much power to generalise to the greater population.

Another limitation of the study is possibly the study design: as discussed in the methods and materials, pre-test/post-test study designs are defined by Polgar and Thomas (2013) as a type of study in which measurements of the groups are taken both prior to and following an intervention. This allows the direct comparison of pre-intervention and post-intervention results for individual subjects and groups of subjects. A pre-test/post-test study design was chosen as it would best answer the question of where change needed to be measured or observed due to an intervention. This design also allowed the participants to act as their own controls. Since the participants were asked the same questions, this could be seen as a manner of biasing the results since the subjects were made aware of the issues which could mimic the effect of the intervention.

The duration of NMES applied to the anterior neck is an important factor to take into account when trying to determine outcome effects: in this study, limited time was available for the collection of the data due to access to a single NMES device, compliance with TAH availability and participant availability. These constraints led to mixed data compared as a group and might have affected the power of the data collected. In this study only 14 minutes of NMES per participant were administered unlike the conventional 60minute duration as suggested in the VitalStim® Therapy System manual (Wijting & Freed, 2003). Although no standardised stimulation times are available, in other studies, it was reported that daily sessions of 60 minutes of stimulation for at least 5 days would provide the required beneficial effects of NMES (Oh et al., 2007). Having only used 14 minutes of stimulation in our study raises the question whether a different data set would have been generated had longer sessions been applied?

The intensity of NMES applied to the anterior neck goes hand in hand with the optimal duration applied. In the literature some contradictory findings have been reported: Doeltgen et al. (2010) found that with maximal intensities of NMES, a positive effect on the HLC was observed whereas Humbert et al. (2006) found the opposite. This study followed the VitalStim® Therapy System protocol for determining the intensity per individual. These intensities differ significantly between each participant and may have resulted in different outcomes accordingly. We do acknowledge this as one of the major limitations of the current study.

Since the study was conducted in healthy young adults, we do also acknowledge the fact that had this study been conducted in patients with swallowing disorders using the same protocol (duration, intensity, etc.), very different data could have been generated. However it was not the aim of the study: we wanted to generate normative swallowing parameters and measurements in order to compare to patients' data. This would obviously be the aim of future studies.

5.5. Future Directions

Although this study did not aim at using the time taken per swallow into account, it might be argued that the time differences that were observed between each time point (pre-NMES compared to post-NMES) may have contributed to the physiological effect of a single NMES session on the HLC. This would be relevant due to the muscle fibre composition of the swallowing muscles: in normal physiology, it is known that the exercise intensity determines the musculature contraction speed. Since this was not accounted for in the current study, it would be important to have this measurement as a covariate in future studies.

The intensity of NMES applied to each subject was determined individually in that each subject reported a "comfortable" level of stimulation. It is evident that the level of stimulation through the VitalStim® Therapy system showed recorded differences of intensities amongst genders as shown in Table 16 and Appendix H. The effects of stimulation intensities was not analysed as a contributing factor on the outcome measurements but we are uncertain whether the differences in the intensities contributed to the results observed. For instance, the possible correlation between gender NMES tolerances might be linked to submental adipose tissue differences or neurological differences between genders.

A single NMES session in healthy individuals might cause lowering of the HLC directly post-NMES, but this effect might be due to fatigue of the HLC after such electrical stimulation. If one considers a longer NMES duration over a prolonged period for physiological adaptation to take place one might find that elevation of the HLC might improve. Similarly anterior movement of the HLC seems to be unaffected post-NMES, but might change its movement pattern over prolonged NMES. Further research on the long term effect and longevity of NMES as treatment needs to be investigated.

Additional investigation would be warranted in order to determine the optimal NMES duration and intensity applied to the anterior neck for rehabilitation. This controversial area of research is still highly debated in the literature and needs further investigation (Heck et al., 2012).

CHAPTER 6: CONCLUSION

This study generated normative data from a cohort of young adults with a limited age range that hasn't been explored to date. It showed that NMES affects the HLC by lowering the elevation thereof while leaving the anterior movement unaffected. This may be seen as a negative outcome long term in that, in patients with swallowing disorders, one would ultimately want to improve the swallowing mechanism and prevent any complications linked to the swallowing difficulties. A single session of NMES leads to the elevation of the HLC but negatively affects the resting position of the HLC post stimulation. This negative impact should be taken into account when using this therapeutic management approach in dysphagic patients.

It is also suggested that repetitive sessions of stimulation using NMES is ultimately the ideal protocol to follow in order to achieve the desired permanent shift in the muscular control of the HLC for the effective management of dysphagia.

Future studies should consider the impact of stimulation intensities, duration of each session as well as the time for the adaption of the muscles post-stimulation may impact on the clinical benefit derived from NMES. Furthermore, differences between devices (external surface versus internal surface application) would need to be evaluated to account for differences in outcomes.

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APPENDIX A: ETHICS LETTER



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Approval Notice New Application

27-Mar-2014
Basson, Tobias TJ

Ethics Reference #: S13/09/172

Title: Changes in Hyo-Laryngeal elevation post-Pharyngeal Electrical stimulation

Dear Mr. Tobias Basson,

The **New Application** received on **30-Sep-2013**, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on **26-Mar-2014** and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: **26-Mar-2014 -26-Mar-2015**

Please remember to use your **protocol number (S13/09/172)** on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired.

The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Included Documents:

DEC LETTER DU PLESSIS

CV TB

APPLIC FORM

PROTOCOL

SYNOPSIS

CHECKL

DEC LETTER MP

DEC LETTER TB

IC FORM

CV DU PLESSIS

CV MP

Sincerely,

Mertrude Davids
HREC Coordinator
Health Research Ethics Committee 2

Investigator Responsibilities

Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

1. **Conducting the Research.** You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.
2. **Participant Enrolment.** You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.
3. **Informed Consent.** You are responsible for obtaining and documenting effective informed consent using **only** the HREC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.
4. **Continuing Review.** The HREC must review and approve all HREC-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period**. Prior to the date on which the HREC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur**. If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC office immediately.
5. **Amendments and Changes.** If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written HREC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.
6. **Adverse or Unanticipated Events.** Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the HREC within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the HRECs requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch University Health Research Ethics Committee Standard Operating Procedures www.sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.
7. **Research Record Keeping.** You must keep the following research-related records, at a minimum, in a secure location for a minimum of fifteen years: the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC
8. **Reports to the MCC and Sponsor.** When you submit the required annual report to the MCC or you submit required reports to your sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.
9. **Provision of Emergency Medical Care.** When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognised as research nor will the data obtained by any such activities should it be used in support of research.
10. **Final reports.** When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.
11. **On-Site Evaluations, MCC Inspections, or Audits.** If you are notified that your research will be reviewed or audited by the MCC, the sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.

APPENDIX B: PARTICIPANT INFORMED CONSENT

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: CHANGES IN HYO-LARYNGEAL ELEVATION POST-PHARYNGEAL ELECTRICAL STIMULATION.

ETHICS REFERENCE NUMBER: S13/09/172

PRINCIPAL INVESTIGATOR: MR TJ Basson

ADDRESS: STELLENBOSCH UNIVERSITY
FACULTY OF MEDICINE AND HEALTH SCIENCES
DIVISION OF MEDICAL PHYSIOLOGY
FRANCI VAN ZIJL DRIVE
7500

CONTACT NUMBER: 074 840 8474

E-MAILADDRESS: tjbasson@sun.ac.za

You are being invited to participate in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- The study will be conducted at Stellenbosch University Tygerberg Medical Campus (SUTMC), with thirty participants (15 male and 15 females) aged between 18–25 years.
- The aim of this study is to determine the effect that neuromuscular electrical stimulation (NMES) has on the muscles of the throat (or pharynx) in healthy individuals with a normal swallow. This will help dysphagia practitioners to treat people who have swallowing disorders (dysphagia).
- Once screened by a Speech Therapist (ST) only 15 male and 15 female participants, who meet the inclusion criteria, will be selected to participate in the study.
- Study procedures, expectations and risks will be clearly explained and informed consent, as well as participant declaration and clinical documentation will be completed.
- You will be expected to swallow half a glass of water during a video-recorded x-ray test (called a videofluoroscopic swallow study (VFSS)) the water will contain barium powder which will make the water visible during the x-ray test. This test will be conducted by a Speech Therapist, a Radiographer and a Radiologist. The duration of the test and during which time you will be exposed to radiation/x-ray lasts is for three (3) to five (5) seconds.
- These x-ray images will be loaded onto PACS to be analysed for this study.
 - Measurements will be done using PACS and computer software to calculate how the hyoid bone which is just above the voice box (larynx) moves up and forward.

Why have you been invited to participate?

- As a healthy individual aged between 18-25 years, you qualify to participate in the present study. For convenience purposes it was decided to recruit participants from the Stellenbosch University, Faculty of Medicine & Health Sciences.

What will your responsibilities be?

- It will be expected from each participant to adhere to the testing schedules arranged for their convenience.

DATE	25 July 2014	30 July 2014	31 July 2014	
TIME	To be confirmed	To be confirmed	To be confirmed	To be confirmed
LOCATION	SUTMC, Tygerberg Student Centre, 2 nd Floor, Mankadan Room	Tygerberg Hospital, 4 th Floor, Radiology Reception		
PROCEDURE	Baseline swallowing assessment	1 st VFSS	NMES	2 nd VFSS
DURATION	10 min	6 min	20 min	6 min

- Follow all clinical procedures as explained to by qualified staff.
- Notify the principal investigator of any problems while participating in the study.
- Male participants will be required to shave the area of electrode placement, i.e. the under surface of the chin and jaw area. This should not be done immediately before the electrical stimulation session, as the skin might be sensitive.

Will you benefit from taking part in this research?

- Participants will receive a screening test for their swallowing.
- Participants will be part of valuable research in the field of dysphagia/swallowing disorders.
- People with dysphagia will benefit from the outcomes of this study.

Are there any risks involved during participation in this research?

- During the videofluoroscopic swallow study, participants will be exposed to a few seconds of radiation. Strict safety procedures will be implemented and radiation will be kept to the minimum exposure as determined by the Radiologist.
- Participants will receive low voltage, comfortable levels of electrical stimulation to the muscles of the pharynx. This will be conducted by a qualified Speech Therapist who is a practitioner trained in the use of pharyngeal electrical stimulation. Strict safety procedures will be implemented to prevent any adverse effects of over stimulation.

If you do not agree to take part, what alternatives do you have?

- Participants can withdraw from the study at any time. This will not affect you negatively in any way.

Who will have access to your medical records?

- Participants will receive a number when enrolled into the study. All participants will remain anonymous. The Speech Therapists who screen participants will be selected randomly by using their allocated numbers. Confidentiality of participant details and results remain throughout the study.
- Only the principal investigator will have access to participant details. Participant details remain confidential and will be kept anonymous throughout the study as names will be replaced by numbers allocated to participants.

What will happen in the unlikely event of some form of injury occurring as a direct result of your taking part in this research study?

- There are no known injuries as a result of either pharyngeal electrical stimulation or the videofluoroscopic swallow study.

Will you be remunerated to take part in this study and are there any costs involved?

- Yes, you will be remunerated to take part in the study. Remuneration of R150.00 will be received by each participant and there will be no costs involved for you if you do take part.

Is there anything else that you should know or do?

- You should inform your family practitioner or usual doctor that you are taking part in a research study.
- You should also inform your medical insurance company that you are participating in a research study.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled: **CHANGES IN HYO-LARYNGEAL ELEVATION POST-PHARYNGEAL ELECTRICAL STIMULATION.**

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) on (date) 2014.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I (name) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above

- I did/did not use an interpreter. (If an interpreter is used then the interpreter must sign the declaration below.

Signed at (place) on (date) 2014.

.....
Signature of investigator

.....
Signature of witness

Declaration by interpreter

I (name) declare that:

- I assisted the investigator (name) to explain the information in this document to (name of participant) using the language medium of Afrikaans/Xhosa.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (place) on (date)

.....
Signature of interpreter

.....
Signature of witness

APPENDIX C: RESEARCH POSTER**Division of Medical Physiology – Stellenbosch University****TITLE OF THE RESEARCH PROJECT:****CHANGES IN HYO-LARYNGEAL ELEVATION POST-PHARYNGEAL ELECTRICAL STIMULATION.****PRINCIPAL INVESTIGATOR: MR TJ BASSON****ADDRESS:** *STELLENBOSCH UNIVERSITY**FACULTY OF MEDICINE AND HEALTH SCIENCES**DIVISION OF MEDICAL PHYSIOLOGY**FRANCIE VAN ZIJL DRIVE**7500***Research Project:**

Participants are required to participate in research involving measurement of hyoid bone movement post-pharyngeal electrical stimulation

Benefits to participants:

- Be part of a valuable study that will contribute to the field of speech pathology regarding rehabilitation of swallowing disorders.
- Evaluation of effective swallow.
- Remuneration of R150.

Participants will be screened by a qualified speech therapist. Participants will then undergo a videofluoroscopy swallowing study (VFSS) pre- and post- neuromuscular electrical stimulation (NMES).

DATE	25 July 2014	18 August 2014	19 August 2014	
PROCEDURE	Baseline swallowing assessment	1 st VFSS	NMES	2 nd VFSS
DURATION	10 min	6 min	20 min	6 min

Who will be accepted?

- Healthy young adults aged between 18-25 years.
- No history with swallowing difficulty or injury to the swallowing area.

To volunteer for the study please contact:

- **Mr TJ Basson:** tjbasson@sun.ac.za / Cell 074 840 8474
- **Prof. M Pillay:** PILLAYM1@ukzn.ac.za
- **Prof Stefan du Plessis:** ssdp@sun.ac.za

Be part of this unique study and contribute to valuable data to the field of Speech Pathology and Medical Physiology!

**APPENDIX D: SWALLOWING SCREENING TOOL
DYSPHAGIA SCREENING TOOL (DST)**

Participant Number:		Date:	25/07/2014
Gender:		Time:	
Age:		Submental skinfold	mm

Screening Items	1	2	3	4
1. Level of Consciousness 6. Easily roused and remains alert at least 15 minutes (assessment should not continue if insufficiently alert).	YES		NO	
2. Is there any history difficulty swallowing?		YES		NO
3. Sitting Tolerance and Head Control 7. Should be able to maintain 90 degree sitting position with chin at 90 degree to the neck (may be supported).	YES		NO	
4. Swallow. Ask the participant to swallow and observe for a. Lip closure b. Absence of drooling c. Laryngeal cartilage (superior and anterior movement)	a) YES b) YES c) YES		a) NO b) NO c) NO	
5. Are there any visible signs of aspiration? a. Cyanosis b. Difficulty breathing associated with swallowing c. Gurgling respirations d. Coughing on own secretions		a) YES b) YES c) YES d) YES		a) NO b) NO c) NO d) NO
6. Trigeminal nerve function: a. Ask: Has the sense of taste diminished? b. Ask to clench teeth and palpate externally for strength. Is there weakness on one or both sides?		a) YES b) YES		a) NO b) NO
7. Facial nerve function: a. Ask to smile, show his teeth, and puff his cheeks out. Is there any weakness/ asymmetry?		YES		NO
8. Glossopharyngeal and vagus nerve function: Ask the patient to say 'ah' while you press a tongue blade firmly down upon the midpoint of the arched tongue and observe the uvula and the soft palate on both sides of the uvula. a. Is the voice 'wet', hoarse or does it have nasal quality? b. Does one side of the palate fall to rise and does the uvula deviate to the opposite side?		a) YES b) YES		a) NO b) NO
9. Hypoglossal nerve function: a. Is the patient able to protrude his tongue, move it from side to side and then to pull back? b. Ask the patient to push the tongue against the inside of each cheek and palpate externally for strength. Is the strength normal and equal on both sides?	a) YES b) YES		a) NO b) NO	
Result/Interpretation	Action			
<i>If only boxes in column 1 and 4 ticked: no swallowing difficulty identified.</i>	<i>Swallow trials completed as per protocol: YES / NO</i>			
<i>If at least one box in column 2 or 3 ticked: patient is NOT safe for oral intake</i>	<i>Request a referral to a Speech Pathologist</i>			

Primary Investigator Signature

Speech Therapist (ST0008796)

The figure illustrates the screening tool. Copyright 2013 by Pillay, M.

APPENDIX E: VFSS PROCEDURE

Videofluoroscopy Protocol

Materials:

- Standard 200ml plastic cup
- Barium powder

1. 22% barium powder suspension was mixed in five millilitres of water
2. Radiographer to prepare equipment for the videofluoroscopic screening.
3. Once the participant has received a unique exam number from radiology it will be recoded.
4. Speech therapist will review age, gender and diagnostic category before proceeding to the VF screening.
5. Participant to be positioned upright in a seated position on a chair (90 degrees , or as close to 90 degrees as possible)
6. The procedure will be explained by the radiographer to the participant.
7. The participant will perform one trail single water swallow and then another recorded single barium solution swallow.
8. The exam will be captured on the PACS data basis.

The figure shows the VFSS procedures. Copyright 2004 by Pillay, M & Hawkins, K.

APPENDIX F: NMES PROCEDURE

NMES Protocol

- Electrode placement:
 - Apply to clean, dry and shaven skin
 - Clean with alcohol swab before placement
 - Maintain head position in neutral position, facing forward
 - Take adipose tissue measurement at lateral laryngeal site of the neck.
 - 2 electrodes on channel 1 are aligned horizontally at or above the hyoid bone
 - 2 electrodes on channel 2 are aligned over the thyrohyoid muscles at the level of the thyroid notch
- Stimulation:
 - Electrical stimulation frequency is set at 80 Hertz
 - Electrical stimulation intensity is determined individually at 75% max (13.3 – 22.3mA for men and 13.88 - 20.12mA for woman)
 - Stimulus duration: 14 consecutive minutes

The figure illustrates the NMES procedures. Adapted from Heck, Doeltgen & Huckabee, (2012).

APPENDIX G: NMES DEVICE SPECIFICATIONS AND PROCEDURES**VitalStim® Therapy System Specifications**

Equipment:

- VitalStim® Therapy System
- Surface electrode electrical stimulation device
- Two channel electrode arrays (Adult size part number: 59000).

Procedure:

- Electrode placement area to be shaved and cleaned with an alcohol swab.
- Attach electrodes to relevant areas and ensure contact by applying additional tape.
- Instruct participant of sensation, progression and anticipated outcome.

Device Specifications:

- Electrical impulse applied as follows:
 - Output waveforms: AC Mode; Rectangular symmetrical biphasic with zero net DC
 - Voltage: 100 Volts Maximum
 - Intensity Control: Dual Intensity potentiometers: 0-25 mA peak current output, adjustable current. Constant current regulation from 0-4000 ohms load minimum.
 - Pulse Rate: Fixed, 80 Hertz (Hz)
 - Pulse Duration: Fixed, 700µSec
 - Pulse Charge: Maximum of 8 µCoulombs under normal operation
 - Output Protection: Under 15µColoumbs charge per pulse with any single component failure.

The VitalStim® Therapy System. The figure illustrates the VitalStim® portable NMES unit with two channel electrode arrays. Copyright 2006 by Yorrick Wijting, PT and Mercy Freed, M.A.

APPENDIX H: NMES INTENSITIES FOR EACH PARTICIPANT

Participant	Gender	NMES Intensity (mA)
1	Male	3.0
2	Male	4.0
3	Male	5.5
4	Female	6.0
5	Male	5.5
6	Male	5.5
7	Female	5.0
8	Female	4.5
9	Female	3.5
10	Male	4.5
11	Female	5.5
12	Male	6.0
13	Male	6.0
14	Female	5.5
15	Female	5.0
16	Female	5.5
17	Male	3.5
18	Female	4.5
19	Female	5.5
20	Female	4.5
21	Female	6.0
22	Male	5.5
23	Female	5.5

†Values are in mA

**APPENDIX I: BASELINE VFSS 1 PRE-NMES (SWALLOWING EXAM 1)
MEASUREMENTS**

Participant	Hyoid Rest Coordinates		Hyoid Elevation Coordinates		Hyoid Decent Coordinates	
	X-distance (mm)	Y-distance (mm)	X-distance (mm)	Y-distance (mm)	X-distance (mm)	Y-distance (mm)
1	38.07	25.73	55.50	29.13	41.10	24.40
2	42.03	19.37	64.77	33.73	45.37	17.67
3	39.27	9.77	56.40	25.23	38.33	25.93
4	44.83	39.17	52.03	51.37	45.70	33.03
5	40.70	17.83	61.67	39.73	41.77	18.87
6	42.13	33.47	57.67	59.67	44.00	45.03
7	39.00	22.00	50.37	38.37	40.03	21.03
8	39.73	26.13	49.33	45.13	39.73	26.47
9	46.10	16.53	59.97	33.93	50.73	17.00
10	60.60	10.93	79.70	29.23	61.57	17.73
11	42.57	17.07	58.93	27.90	46.57	24.60
12	49.83	14.27	64.53	16.67	52.17	13.33
13	33.57	24.60	49.57	45.87	36.60	24.13
14	54.80	33.20	68.07	54.67	56.00	27.67
15	41.67	17.87	59.90	28.60	44.67	15.83
16	37.10	41.07	48.43	48.83	38.80	37.10
17	53.80	13.93	67.80	30.73	55.70	19.57
18	52.00	14.77	69.70	22.80	51.07	6.67
19	51.77	14.70	62.43	38.77	54.80	13.37
20	55.00	19.13	76.70	37.37	56.07	17.83
21	49.33	11.00	67.33	25.33	50.67	9.67
22	46.80	17.73	57.80	32.43	48.43	17.07
Mean	45.49	20.92	60.85	36.16	47.26	21.55
SD	7.05	8.93	8.54	11.04	6.96	8.88
SEM	1.50	1.90	1.82	2.35	1.48	1.89

†Values are in mm

**APPENDIX J: FOLLOW-UP VFSS 2 POST-NMES (SWALLOWING EXAM 2)
MEASUREMENTS**

Participant	Hyoid Rest Coordinates		Hyoid Elevation Coordinates		Hyoid Decent Coordinates	
	X-distance (mm)	Y-distance (mm)	X-distance (mm)	Y-distance (mm)	X-distance (mm)	Y-distance (mm)
1	37.80	14.40	53.40	28.00	39.57	17.50
2	42.70	18.87	66.23	31.63	47.20	13.73
3	37.37	14.87	50.40	22.70	38.67	10.10
4	42.83	14.07	54.87	24.80	45.47	6.70
5	39.83	19.40	59.13	40.17	39.77	18.57
6	41.87	30.80	56.70	52.63	41.23	32.90
7	41.33	9.43	53.13	24.27	42.10	11.83
8	39.23	25.37	50.57	40.40	41.23	22.97
9	45.83	16.67	59.57	29.70	49.57	13.60
10	59.30	14.27	69.43	38.70	57.27	21.70
11	43.27	11.23	54.57	23.77	44.20	13.03
12	48.27	8.57	57.40	10.67	49.23	10.03
13	35.00	22.67	49.10	47.80	38.70	23.97
14	54.77	22.17	73.90	51.23	56.00	23.40
15	42.07	13.47	57.27	25.27	42.67	12.77
16	36.87	28.70	47.70	35.67	38.23	27.67
17	53.07	14.63	68.40	30.07	56.47	17.40
18	48.67	4.40	64.67	14.13	50.30	3.73
19	51.73	0.00	62.07	33.23	55.53	0.00
20	53.37	11.00	73.77	30.07	53.77	10.03
21	52.73	0.00	68.83	13.03	54.27	-5.43
22	44.87	1.70	56.63	12.07	45.17	-4.67
23	37.80	14.40	53.40	28.00	39.57	17.50
Mean	45.13	14.40	59.44	30.00	46.66	13.71
SD	6.71	8.54	7.91	12.00	6.60	9.88
SEM	1.43	1.82	1.69	2.56	1.41	2.11

†Values are in mm